Name : .....

Roll No. : .....

Invigilator's Signature : .....

CS/B.PHARM(N)/SEM-7/PT-706/2011-12

2011
PHARMACEUTICS
(PHARMACEUTICAL TECHNOLOGY)

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) ICH Q3A guidelines provide specifications for
      a) degradation products
      b) new dosage forms
      c) biotechnological products
      d) photostability of drugs.

   ii) Differential scanning calorimetry is mainly used for the measurement of the
      a) excipient compatibility
      b) polymorphisms
      c) particle topography
      d) both (a) and (b)

   iii) Higuchi release kinetics occurs when drug is enclosed by
      a) hydrophilic polymer b) lipophilic polymer
      c) anionic polymer d) cationic polymer.

iv) Effective surface area is

a) the area of solid surface exposed to the dissolution medium

b) the total area of solid surface of any particle

c) both (a) and (b)

d) none of these.

v) The "sink" condition during in vitro drug dissolution study is maintained when

a) $C_s >> C_b$ b) $C_s << C_b$

c) $C_s = C_b$ d) none of these.

vi) For the interpretation of in vitro dissolution data, the number of tablets required in first stage is

a) 6 b) 12

c) 24 d) 20.

vii) Consolidation Index value (%) 5 – 15 shows

a) excellent flow properties

b) good flow properties

c) very poor flow properties

d) very very poor flow properties.

viii) For powder bed diameter of D and bed height of h, the angle of repose could be

a) $\tan^{-1}(2h/D)$ b) $\tan^{-1}(D/2h)$

c) $\tan^{-1}(D/h)$ d) $\tan^{-1}(h/D)$.

ix) Which one is exothermic reaction ?

a) Desolvation b) Solid-solid transition

c) Sublimation d) Crystallization.

x) The optimum stability of aspirin is at

a) pH 2-3 b) pH 4-5

c) pH 6-7 d) none of these.

xi) Carrier linked prodrugs release the active drug by hydrolytic cleavage which is triggered

a) only chemically

b) only enzymaticallyn

c) either chemically or enzymatically

d) none of these.

xii) Regular validation of a system is called

a) concurrent b) process

c) prospective d) retrospective.

GROUP – B

(Short Answer Type Questions)

Answer any *three* of the following. 3 × 5 = 15

2. Describe brain targeted drug delivery through prodrug concept.

3. Enumerate the ICH QIA guidelines for stability testing of new drug and drug products.

4. Explain intra-particle, inter particle and total porosity.

5. Define pK_a. How does it relate with absorption of drugs ? Write the names two instruments which are used for determination of p*Ka*. 1 + 3 + 1

6. Write short notes on effect of Temperature on solubility. How will you determine the E (activation energy) for a compound ?

GROUP – C

(Long Answer Type Questions)

Answer any *three* of the following. 3 × 15 = 45

7. a) Describe the design of USP dissolution rate test apparents type-I type – II with schematic diagram.

   b) Give an outline of the bioavailability testing protocol of a sustained release formulation.

8. What is site master file ? Describe its function in detail.

   3 + 12

9. a) Write down the principles involved in Hydrolysis Reactions involving degradation of various drugs.

   b) Discuss how Procaine and chloramphenicol undergo Hydrolysis and write the methods of prevention from Hydrolysis. 5+ 10

10. What is the inter-relationship between QC, QA and GMP ? What are the objectives of cGMP in pharmaceutical industry ? Write about quality audit in pharmaceutical industry. Why are the elements of GMP ? 2 + 2 + 6 + 5

11. Write notes on any *two* the following : $7\frac{1}{2} + 7\frac{1}{2}$

    a) Importance of microscopy, thermal & X-Ray diffraction analysis in preformulation study

    b) Matrix tablets & osmotically controlled drug release

    c) Microparticulate systems & their evaluation.