Name : .....

Roll No. : .....

Invigilator's Signature : .....

CS/B.PHARM (N)/SEM-7/PT-706/2012-13

2012

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) For the interpretation in the *in vitro* dissolution data, the number of tablets required in second stage (S2) is

      a) 1

      b) 2

      c) 6

      d) 12.

ii) Carrs index 5-15 shows

a) excellent flow properties

b) very poor flow properties

c) poor flow properties

d) good flow properties.

iii) ICH Q3A guidelines provide specifications for

a) degradation products

b) new dosage form

c) biotechnological products

d) photostability of drugs.

iv) The sink condition of *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.

v) Lecithin is an example of

a) water soluble antioxidant

b) oil soluble antioxidant

c) both water and oil soluble

d) none of these.

vi) Phosphate ester of steroidal drug is preferable because

a) low solubility with high chemical stability

b) low solubility with low chemical stability

c) high solubility with high chemical stability

d) high solubility with low chemical stability.

vii) Example of mutual prodrug is

a) Diazepam hydrochloride

b) Benorylate

c) Acyclovir

d) None of these.

viii) Poor flow is indicated when the value of Hausner ratio is

a) < 1·15 b) > 1·25

c) > 1·15 d) < 1·25.

ix) Under sink conditions, the drug concentration in bulk (C_b) is never much greater than

a) 20% of C_s b) 30% of C_s

c) 50% of C_s d) 1% of C_s .

x) β-cyclodextrin is cyclic oligomers of glucose containing glucose residues of

a) 5 b) 8

c) 6 d) 7.

xi) Potentiometric titration is used to determine a drug's

a) partition coefficient

b) pKa

c) solubility

d) true density.

xii) According to ICH Q1A (R2) guidelines, the long-term stability study of tablets should be carried out under the conditions of

a) 30 ± 2°C/65 ± 5% RH

b) 40 ± 2°C/75 ± 5% RH

c) 25 ± 2°C/60 ± 5% RH

d) both (a) and (c).

xiii) Palmitate ester of chloramphenicol is designed for the purpose of

a) reducing gastric irritation

b) reducing pain on injection

c) preventing pre-systemic metabolism

d) masking bitter taste.

xiv) Measure of degree of correctness of a value is called as

a) Precesion b) Selectivity

c) Sensitivity d) Accuracy.

GROUP – B

(Short Answer Type Questions)

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

2. Mathematically prove that

Geometrical surface area (A) = $\frac{6}{\rho} \sum \frac{W_i}{d_i}$

where ρ is the solid density of the sample, W_i is the weight retained on the i^{th} mesh and d_i is the mean diameter of the i^{th} mesh.

3. Enumerate how shelf life is determined by accelerated stability study with necessary graphical presentations.

4. What are the factors affecting the design of an *in vitro* dissolution test ?

5. Define bioavailability and bioequivalence. Lay out a Latin square cross-over diagram for bioequivalence study on three formulations in six volunteers. 2 + 3

6. Define cGMP. Briefly discuss the factors that must be considered to ensure the objectives of GMP. 1 + 4

GROUP – C

(Long Answer Type Questions)

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

7. Define controlled release system. Make a difference between continuous release and pulsatile release. Describe briefly the low density and high density system in GRDDS.

2 + 2 + 8 + 3

8. Define autoxidation. Briefly describe the autoxidation process for an organic molecule. Discuss the factors influencing the oxidation of drugs along with its method of prevention. How can the hydrolytic decomposition of drug be prevented ? 2 + 3 + 5 + 5

9. What do you mean by the term 'process validation' ? Explain different types of process validation. Discuss the process validation methods for the pharmaceutical operations involved in the production tablets prepared by wet granulation technique. 1 + 4 + 10

10. Define prodrug and mutual prodrug. How can the prodrug approach be utilized for site specific drug delivery and improving the bioavailability of drugs through various routes of administration ? 2 + 8 + 5

11. Write note on any *two* of the following : $2 \times 7\frac{1}{2}$

a) Matrix tablets and oral osmotic tablets

b) Vesicular drug delivery systems

c) Drug's solubility and polymorphism as pre-formulation factors.