Name : .....

Roll No. : .....

Invigilator's Signature : .....

CS/B.PHARM(OLD)/SEP.SUPPLE/SEM-7/PT-706/2012

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) Which is more stable polymorphic form of Chloramphenicol palmitate ?

a) *A* b) *B*

c) *C* d) None of these.

ii) The sink condition during *invitro* dissolution study is maintained when

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

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

iii) Which one is the mutual prodrug ?

a) Chloramphenicol

b) Chloramphenicol palmitate

c) Benorylate

d) Diazepam-HCl.

iv) Which antioxidant should be used in aqueous pharmaceutical preparation ?

a) BHT b) BHA

c) Ascorbic acid d) Lecithin.

v) The equation involved in temperature accelerated stability study is

a) Arrhenius b) Braggs

c) Noyes-Whitney d) Peppas.

vi) Which one of the following is a water soluble polymer ?

a) Sodium alginate

b) Polystyrene

c) Polymethylmethacrylate

d) PVC.

vii) Preformulation study is done in

a) *QA* department b) Production dept.

c) R & D dept. d) QC dept.

viii) Potential bioavailability problems may exist when a drug substance has an aqueous solubility of

a) 10 mg/ml b) less than 1 mg/ml

c) less than 0·5 mg/ml d) less than 1 g/ml.

ix) Stability testing of new drug substances and products are described in
   a) ICH Q1B b) ICH Q1C
   c) ICH Q6A d) ICH Q1A.

x) Validation should be done for
   a) four primary batches b) minimum 3 batches
   c) minimum 2 batches d) a single batch.

xi) Nanoparticles are having submicron particles in the nanometer size range of
   a) 20 to 15000 nm b) 10 to 1000 nm
   c) 10 to 10000 nm d) 1 to 1000 nm.

xii) Transdermal delivery systems are topically administered medicaments that deliver drugs for
   a) local effect
   b) systemic effect
   c) both (a) and (b)
   d) either local or systemic effect.

GROUP – B

(Short Answer Type Questions)

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

2. Define bioavailability and bioequivalence. Layout a Latin square cross-over diagram for bioequivalence study on three formulations in six volunteers.

3. Give the ICH guidelines for stability testing of pharmaceuticals.

4. Write in brief about the process validation method for pharmaceutical operations involved in tablet production.

5. What is Carr's index ? How to determine bulk density ? Define Hausner ratio. 2 + 2 + 1

6. Write short notes on racemization of polymorphism. 2 + 3

GROUP – C

(Long Answer Type Questions)

Answer any *three* of the following questions.

$3 \times 15 = 45$

7. What are GMP and QA ? Write down the objectives of GMP. Discuss the factors associated with GMP to obtain a zero defect pharmaceutical product. 2 + 3 + 10

8. What is the importance of preformulation study ? Discuss the effect of polymorphism and crystallinity of drug on formulation stability and bioavailability. Write the analytical methods for the detection of these physical properties.

3 + 7 + 5

9. What is the difference between validation & calibration ? What is the basic principle of validation ? What is process validation ? What are the different phases of process validation ? Write about the process validation of tablets.

2 + 2 + 1 + 3 + 7

10. What is stability ? What are the various routes of drug degradation ? Write about the physical decomposition of pharmaceutical products. Briefly discuss hydrolysis as a major drug degradative pathway. 2 + 2 + 5 + 6

11. Explain the terms absolute bioavailability and relative bioavailability. Explain minimum effective concentration, C_{max} , T_{max} , onset and duration of drug action and therapeutic intensity of a drug by sketching a drug concentration *vs* time curve. $(2 \times 2\frac{1}{2}) + 10$