Name : .....

Roll No. : .....

Invigilator's Signature : .....

CS/B.PHARM (O)/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 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) Which antioxidant should be used in aqueous pharmaceutical preparation ?

   a) BHT b) BHA

   c) Ascorbic acid d) Lecithin.

iii) The equation involved in temperature accelerated stability study is

a) Arrhenius b) Braggs

c) Noyes-Whitney d) Peppas.

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

a) Sodium alginate

b) Polystyrene

c) Polymethylmethacrylate

d) PVC.

v) Stability testing of new drug substances and products are described in

a) ICH Q1B b) ICH Q1C

c) ICH Q6A d) ICH Q1A.

vi) Validation should be done for

a) four primary batches b) minimum 3 batches

c) minimum 2 batches d) a single batch.

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) 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.

GROUP – B

(Short Answer Type Questions)

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

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

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

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 & polymorphism. 2 + 3

GROUP – C

(Long Answer Type Questions)

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

7. 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.

$2 + 2 + 1 + 3 + 7$

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

9. Describe the advantages & disadvantages of controlled release formulation. Discuss the different methods of preparation of controlled release formulation. $8 + 7$

10. Explain the terms 'absolute bio-availability' and 'relative bio-availability'. 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. $(2 \times 2\frac{1}{2}) + 10$