Name : .....

Roll No. : .....

Invigilator's Signature : .....

CS/B.Pharm(OLD)/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) Dissolution is affected by

   a) surface area b) temperature

   c) viscocity d) none of these.

   ii) Validation study is done by

   a) Q.A. department b) Production department

   c) Q.C. department d) none of these.

   iii) The sink condition during in vitro dissolution study is maintained when

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

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

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iv) Stability testing of new drug substances & products is described in

a) ICH Q1B b) ICH Q1C

c) ICH Q6A d) ICH Q1A.

v) Preformulation study is done is

a) Q.A. department b) Production department

c) R & D department d) Q.C. department.

vi) Validation should be done for

a) four primary batches b) minimum 3 batches

c) minimum 2 batches d) a single batch.

vii) Which one is the mutual prodrug ?

a) Chloramphenicol

b) Chloramphenical palmitate

c) Benorylate

d) Diazepam-HCl.

viii) The equation involved in temperature accelerated stability study is

a) Arrhenius b) Braggs

c) Noyes-Whitney d) Peppas.

ix) Which is an example for cationic surfactant ?

a) Benzalkonium chloride

b) Polysorbate 80

c) Sodium lauryl sulphate

d) Sorbitol mono-oleate.

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x) 'Store in a cool place' means

a) an air-conditioned area at 10°C

b) a refrigerator at 15°C

c) a place whose temperature is set at 5°C

d) room temperature at 25°C.

xi) Liposomes are particles in the size range of

a) 25 to 5000 nm

b) 10 to 10000 nm

c) 1 to 1000 nm

d) 20 to 15000 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. Discuss the effects of physical form in pre-formulation studies.

5. Discuss the methods of prevention of oxidative degradation.

6. Describe accelerated stability testing with its limitations.

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GROUP – C

(Long Answer Type Questions)

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

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

8. 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

9. Define controlled release dosage form. Describe design of controlled release or sustained release dosage form based on zero order release approximation. 4 + 11

10. What is 'Schedule M' under Drugs and Cosmetics Act of India, 1940 ? Write down the activities of quality assurance department. How is quality audit performed in the storage area of pharmaceutical Industry ?

11. Describe the factors affecting the design of in vitro dissolution rate test apparatus. Describe any one dissolution apparatus in detail. Give a brief outline for the bio-availability testing protocol of a sustained release formulation. 4 + 5 + 6

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