CS/B.PHARM (SUPPLE)/SEM-7/PT-706/09

PHARMACEUTICS (Pharmaceutical Technology) (SEMESTER - 7)

1. ....
Signature of Invigilator

2. ....
Signature of the Officer-in-Charge

Reg. No. | | | | | | | | | | | | | | | |

Roll No. of the Candidate | | | | | | | | | | | | | | | |

CS/B.PHARM (SUPPLE)/SEM-7/PT-706/09

ENGINEERING & MANAGEMENT EXAMINATIONS, JULY – 2009

PHARMACEUTICS (Pharmaceutical Technology) (SEMESTER - 7)

Time : 3 Hours] [Full Marks : 70

INSTRUCTIONS TO THE CANDIDATES :

1. This Booklet is a Question-cum-Answer Booklet. The Booklet consists of **32 pages**. The questions of this concerned subject commence from Page No. 3.
2. a) In **Group – A**, Questions are of Multiple Choice type. You have to write the correct choice in the box provided **against each question**.
   b) For **Groups – B** & **C** you have to answer the questions in the space provided marked 'Answer Sheet'. Questions of **Group – B** are Short answer type. Questions of **Group – C** are Long answer type. Write on both sides of the paper.
3. **Fill in your Roll No. in the box** provided as in your Admit Card before answering the questions.
4. Read the instructions given inside carefully before answering.
5. You should not forget to write the corresponding question numbers while answering.
6. Do not write your name or put any special mark in the booklet that may disclose your identity, which will render you liable to disqualification. Any candidate found copying will be subject to Disciplinary Action under the relevant rules.
7. **Use of Mobile Phone and Programmable Calculator is totally prohibited in the examination hall.**
8. You should return the booklet to the invigilator at the end of the examination and should not take any page of this booklet with you outside the examination hall, **which will lead to disqualification**.
9. Rough work, if necessary is to be done in this booklet only and cross it through.

No additional sheets are to be used and no loose paper will be provided

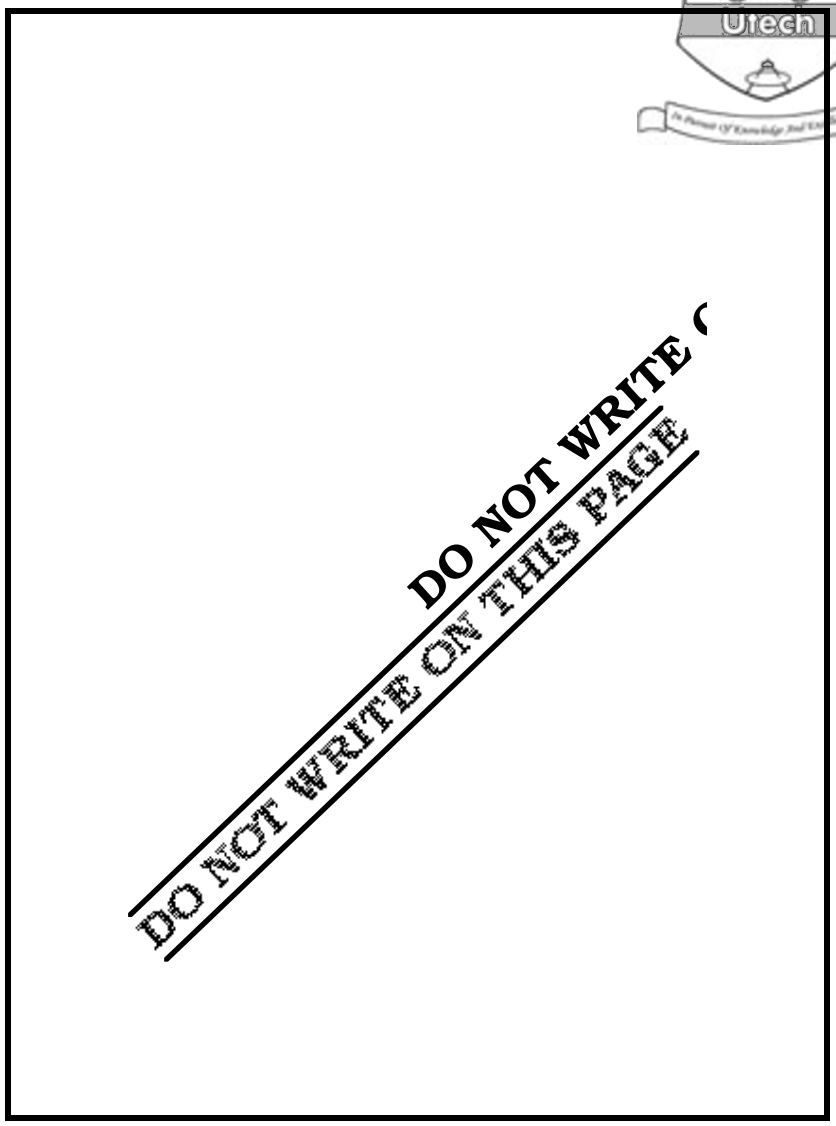
FOR OFFICE USE / EVALUATION ONLY

Marks Obtained

	Group – A										Group – B			Group – C				
Question Number																	***Total Marks***	***Examiner's Signature***
Marks Obtained																		

....
Head-Examiner/Co-Ordinator/Scrutineer

S-53026 (28/07)



CS/B.PHARM (SUPPLE)/SEM-7/PT-706/09

PHARMACEUTICS (Pharmaceutical Technology)

SEMESTER - 7

Time : 3 Hours] [Full Marks : 70

GROUP – A

(Multiple Choice Type Questions)

1. Choose the correct alternatives for any *ten* of the following : 10 × 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) Nanoparticles are 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. ☐

viii) 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.

☐

ix) Dissolution is affected by

a) surface area b) temperature

c) viscosity d) none of these. ☐

x) An example of a cationic surfactant is

a) Benzalkonium chloride b) Polysorbate 80

c) Sodium lauryl sulphate d) Sorbitol mono-oleate. ☐

xi) '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. ☐

xii) An example of polymer used for enteric coating of tablet is

a) Hydroxy propyl cellulose

b) Hydroxy propyl methyl cellulose

c) Hydroxy ethyle cellulose

d) Hydroxyl propyl methyl cellulose phthalate.

GROUP – B

(Short Answer Type Questions)

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

2. Explain the terms 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. Discuss the effects of physical form in pre-formulation studies.

GROUP – C

(Long Answer Type Questions)

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

6. 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

7. 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

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. 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.

$(2 \times 2\frac{1}{2}) + 10$

END