CS/M.Pharm (Pharmaceutics/Pharmacology/Pharmaceutical Chemistry)/SEM-2/MPT-212/09

PROCESS VALIDATION & CGMP (SEMESTER - 2)

1. ....
Signature of Invigilator

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

Reg. No.

Roll No. of the Candidate

CS/M.Pharm (Pharmaceutics/Pharmacology/Pharmaceutical Chemistry)/SEM-2/MPT-212/09

ENGINEERING & MANAGEMENT EXAMINATIONS, JULY – 2009

PROCESS VALIDATION & CGMP (SEMESTER - 2)

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

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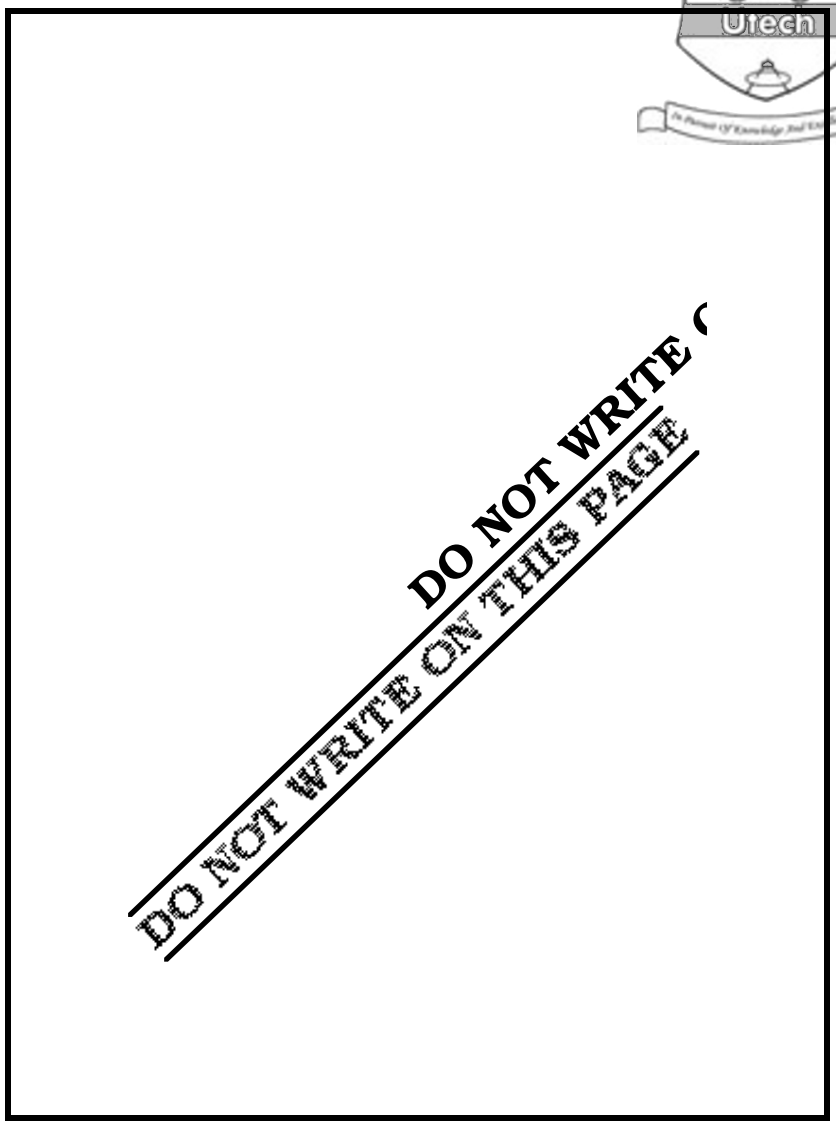
Marks Obtained

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

....

Head-Examiner/Co-Ordinator/Scrutineer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SEMESTER - 2

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GROUP – A

(Multiple Choice Type Questions)

1. Choose the correct alternatives for any *ten* of the following : 10 × 1 = 10

i) When the population is large, sampling is done from

a) each of the units

b) first ten units

c) last ten units

d) the units at random in statistical way. ☐

ii) An ideal analytical method should be

a) biased, precised and accurate

b) unbiased, precised but not accurate

c) unbiased, accurate but not precise

d) unbiased, precised and accurate. ☐

iii) Quality Management System — Requirements, guideline are described in

a) ISO 19011 b) ISO 14001

c) ISO 9001 : 2000 d) none of these. ☐

iv) A Para II filing for the launch of a Generic Drug is made when

a) the drug is not been patented

b) the drug is already off patent

c) patent is not infringed or is invalid

d) none of these.

v) Number of healthy volunteers required for Phase-I clinical trial is

a) 200 – 800 b) 2,000 – 8,000

c) 20 – 80 d) none of these.

vi) Number of rotation used to conduct a friability test is

a) 100 revolution per minute

b) 100 revolution per 10 minutes

c) 100 revolution per 4 minutes

d) 100 revolution per 5 minutes.

vii) To find out which process variable are critical for the product attributes ..... needs to be studied.

a) Process validation b) Process characterization

c) Structural organization d) None of these.

viii) Your company is going to buy a tablet machine, what kind of qualification exercise you will perform at first ?

a) Performance qualification b) Installation qualification

c) Operational qualification d) Design qualification.

ix) A batch production record alongwith the 'COA' is released by the head of

a) Quality control department b) Production department

c) Q.A. department d) Factory Management. ☐

x) Cross contamination and Mix-up at production site is prevented by adopting.

a) GCP b) GLP

c) GMP d) None of these. ☐

xi) Para-IV filing is related to which of the following ?

a) ANDA b) NDA

c) IND d) GCP. ☐

xii) DMF may be defined as

a) drug manufacturing file b) drug master file

c) drug maintenance file d) all of these. ☐

xiii) The average velocity of HEPA filter under laminar airflow is

a) 90 ft/min b) 100 ft/min

c) 120 ft/min d) 150 ft/min. ☐

GROUP – B

(Short Answer Type Questions)

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

2. What are the basic methods used for assay of drug molecules ?

3. Write a short note on 'WHO Certification Scheme'.

4. Write a brief note on the Requirement of GLP.

5. Write a short note on the importance of quality audit in a pharmaceutical industry.

GROUP – C

(Long Answer Type Questions)

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

6. What are the different parameters required to fulfill the method validation ? What is the basic difference between Repeatability and Reproducibility ? How do you determine Linearity and Recovery for a method ? 5 + 2 + 8

7. What is quality audit ? Write down different types of quality audit. Why is auditing necessary ? What is horizontal auditing ? 2 + 8 + 3 + 2

8. a) Why Analytical Method Validation is required ? 3

   b) Describe each characteristics of an analytical procedure that you are going to validate. 12

9. a) What do you mean by DMF ? 3

   b) Describe its importance in NDA process. 4

   c) What are 'Open part and close part' of DMF ? 4

   d) Write a note on orange book. 4

10. a) What are the 'quality management system' approaches that you can undertake, for establishing an effective Quality Management System ? 8

    b) What are the steps that you would take for certification of ISO 9001 : 2000, for your organization. 7

END