Name : .....

Roll No. : .....

Invigilator's Signature : .....

CS/M.PHARM/SEM-2/MPT-212/2013

2013

PROCESS VALIDATION AND CGMP

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 × 1 = 10

   i) As per 21 CFR part 11, the closed system is defined as environment in which system access is controlled by persons who are responsible for the content of ..... that are on the system.

      a) Paper records b) Electronic records

      c) All of these d) None of these.

   ii) A cleaned equipment needs to be inspected for cleanliness

      a) every 7 days b) every 30 days

      c) every 6 months d) before use.

iii) Quality control testing calculations needs to be verified for accuracy by

a) 2nd person

b) by QA head only

c) by computer

d) by QA for validation batches only.

iv) Self contained and dedicated manufacturing facility is required for the manufacture of

a) Penicillins b) Vitamins

c) Nutraceuticals d) Anaesthetic.

v) DQ, IQ, OQ & PQ are associated with

a) Analytical methods

b) Production process

c) Equipment and machines

d) Calibration.

vi) In India which organization is responsible for distributing he Standards of ISO ?

a) BIS b) CDSCO

c) ISI d) DST.

vii) From a large propulation, sampling is done from

a) alternate units

b) every 10th unit

c) every 20th unit

d) units at random in statistical way.

viii) FDA guidelines state that two formulations are bio-equivalent if their rate and extent of absorption differ by

a) + 25% / – 20% b) + 20% / – 25%

c) + 25% / – 30% d) + 30% / – 30%.

ix) Exclusive Marketing Right (EMR) is related to

a) Branded Drugs b) Generic drugs

c) Proprietary medicines d) none of these.

x) The measure of exactness of the analytical method is known as

a) Precision b) Selectivity

c) Accuracy d) Ruggedness.

xi) CBER is responsible for ensuring safety and efficacy of

a) Medical devices b) Vaccines

c) New drugs d) None of these.

xii) Ideal storage condition of capsule is

a) 45% humidity b) 25% humidity

c) 75% humidity d) 100% humidity.

GROUP – B

(Short Answer Type Questions)

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

2. Write a note on sampling and sampling plan.

3. Write short notes on 'Placebo' in clinical trial. Discuss the importance of 'Informed consent'. 2 + 3

4. Mention the eight Management Principles of ISO 9001:2008.

5. What is Electronic Signature ?

6. With suitable examples describe the difference between Open system and Closed system with reference to 21 CFR part 11.

GROUP – C

(Long Answer Type Questions)

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

7. Define the term 'Validation'. Classify the types of Validation. Explain different types of process validation as carried out in a pharmaceutical company. "Retrospective validation is not a quality assurance measure in itself." Justify. 1 + 4 + 6 + 4

8. a) What are the aims of new drug discovery ?

   b) Give the schematic representation of new drug discovery process.

   c) Write in detail about the general information of Investigational New Drug application. 2 + 6 + 7

9. What is Quality Audit ? Explain different types of quality audit. Prepare a checklist for auditing a Raw Material Store of a pharmaceutical manufacturing concern. 2 + 5 + 8

10. Give an outline on the selection of an ideal premises and location for a Beta-lactum parenteral unit. 'Control of contamination is the basis of cGMP.' Justify. Discuss the factors to be considered for selection of an efficient tablet compression machine. 5 + 4 + 6

11. a) What is Quality ?

    b) What is GMP ?

    c) What is GLP ?

    d) What are the role of a QC dept. in a GMP set up ?

    e) Discuss Product recall from market. 2 + 2 + 2 + 5 + 4