*Name* : .....

*Roll No.* : .....

*Invigilator's Signature* : .....

**CS/M.PHARM/SEM-1/MPT-115(2)/2012-13**

**2012**

# QUALITY ASSURANCE-II

*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

## ( Objective Type Questions )

1. Answer any *ten* of the following : 10 × 1 = 10

A) Choose the correct alternatives for the following :

i) 21 CFR.211 is

a) GLP

b) *c*GMP

c) GMP, Drugs ( General )

d) GMP, Drugs ( Finished pharmaceuticals ).

ii) Both Indian and WHO GMP state that validation should be considered as

a) one-off exercise

b) on going program

c) first implementation

d) none of these.

iii) Prospective Process Validation runs will be required

a) before the product is launched in the market

b) after the product is launched in the market

c) after any complaints received from the market

d) any time of processing of product.

iv) The size laboratory pilot batch will be

a) 10X b) 100X

c) 1000X d) 10000X.

v) 'Product Recall', this element appears in

a) Schedule *Y*

b) Schedule *X*

c) Revised schedule *M*

d) Schedule *N*.

vi) Revised schedule *M* recommends Potable water should not contain which one of the following pathogens ?

a) *E.coli*

b) Lactobacillus

c) S. Sacharomyces

d) None of these.

B) Fill in the blank :

vii) Quality Assurance = GMP + GLP + .....

C) Answer very briefly :

viii) What is AQL ?

ix) Name any two basic phases of Quality Audit.

x) What is the endotoxin level of water used in pharmaceutical products ?

xi) What is the level-1 document of the organization ?

## GROUP – B

### ( Short Answer Type Questions )

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

2. Write a short on Qualifications of Instrument Validation.

3. What is quality audit ? Explain different types of quality audit.

4. What do you mean by Pareto principle ?

5. Write in brief about good warehousing practice.

6. Describe quality review of the finished products.

## GROUP – C

### ( Long Answer Type Questions )

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

7. What are the different steps to validate an analytical method and what are the different steps to audit of analytical method ? 5 + 10

8. a) Give an account for validation of steam sterilization process.

   b) Define *F*-value, *D*-value and *Z*-value. 10 + 5

9. a) Write a short on Fish-bone diagram.

   b) Describe Validation Master Plan.

   c) What may be the possible reasons for product recall ?

   6 + 6 + 3

10. a) Describe in detail about Batch Release Documents of Finished goods.

    b) Write down the steps involved in Product Recall. 8 + 7

11. Write short notes on the following : 5 + 5 + 5

    a) Quality control of non-clinical testing

    b) Waste disposal

    c) Quality control documentation.