



Name :

Roll No. :

Invigilator's Signature :

CS/M.Pharm/SEM-1/MPT-115(2)/2010-11

2010-11

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) Logistical support is associated with

- | | |
|----------------|----------------------|
| a) maintenance | b) availability |
| c) reliability | d) trouble shooting. |

ii) Quality system model for quality assurance in production and installation is

- a) ISO 9002 — 1987
- b) ISO 9001 — 1987
- c) ISO 9000 — 1987
- d) ISO 9003 — 1987.



- iii) A state resembling ethyl alcohol intoxication occurs in
- a) cyanide poisoning
 - b) carbon monoxide poisoning
 - c) lead poisoning
 - d) arsenic poisoning.
- iv) Class A analytical method is a
- a) method for identity of bulk drugs and / or their formulations
 - b) method for determining concentration of bulk drug or major ingredient in finished dosage form
 - c) method for impurities in bulk drugs and / or their formulations
 - d) method for assessing characteristics of finished dosage form.
- v) Halon extinguishes fire by
- a) displacing oxygen
 - b) binding with oxygen
 - c) reducing temperature
 - d) none of these.



- vi) Endotoxin level in water used in pharmaceutical unit is not more than
- a) 0.15 EU/ml b) 0.20 EU/ml
c) 0.25 EU/ml d) 0.30 EU/ml.

B) Fill in the blanks :

- vii) The ratio of mean time between failures (MTBF) and sum of MTBF plus mean time to repair (MTTR) is called
- viii) The full form of AQL is
- ix) The OC curve is a graph of lot fraction defective versus
- x) Lack of oxygen in the blood or non-delivery of oxygen to the tissues is called
- xi) ISO : 9000 — 2000 is a combined standard which includes ISO — 9002 and
- xii) The full form of EEAS is

GROUP – B

(Short Answer Type Questions)

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

2. Write down the steps applied to the problem of quality in quality control. What are the various aspects to produce the final analytical report ?
3. Write a short note on validation of sterilization methods.

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4. Explain the four quadrants of GLP.
5. What is ISO ? Explain ISO 9000 series of standards.
6. What are the good warehousing practices ?

GROUP – C

(Long Answer Type Questions)

Answer any *three* of the following. $3 \times 15 = 45$

7. What do you mean by validation ? Describe validation policy, documentation, approaches and programs of process validation.
8. What is quality audit ? Explain different types of audit. Write down the principles of auditing.
9. Describe the sampling highlighting different sampling plans, standard sampling plans, the Indian standards and the sampling procedures in pharmaceutical industry.
10. Explain the following :
 - a) Safety policy
 - b) Waste disposal and storage.
11. Write down the classification of different biological products based on immunological principles. Briefly describe the supporting and supplementary guidelines for sterile products.