Name : .....

Roll No. : .....

Invigilator's Signature : .....

CS/M.Pharm/SEM-1/MPT-101(1)/2010-11

2010-11

QUALITY ASSURANCE OF PHARMACEUTICALS

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 : $10 \times 1 = 10$

   i) The efficacy of ethylene oxide as a sterilant include

      a) concentration of the gas

      b) temperature and gas pressure

      c) time of exposure

      d) all of these.

   ii) According to EC GMP guide, a primary packaging materials is

      a) a material that have a direct contact with product

      b) a material that have a indirect contact with product

      c) a material that have a no contact with product

      d) none of these.

iii) The specifications for finished products should include

a) the designated name of the product and the code reference where applicable

b) the formula or a reference

c) the storage conditions and any special handling precautions, where applicable

d) all of these.

iv) The steps of performing quality audit include

a) plan and prepare

b) arrive at site of audit, meet and explain purpose

c) perform audit

d) all of these.

v) Specifications for starting and primary or printed packaging materials should include

a) a description of the materials, including the designated name and the internal code reference, the reference, if any, to a pharmacopoeial monograph, the approved suppliers and if possible, the original producer of the products, a specimen of printed materials

b) directions for sampling and testing or reference to procedures

c) qualitative and quantitative requirements with acceptance limits

d) all of these.

vi) As per GMP for liquid dosage form the floor should be
   a) ordinary painting
   b) terazo tiles
   c) epoxy painting / terazo coved
   d) none of these.

vii) Reprocessing of pharmaceutical product is to be approved by
   a) manufacturing dept.
   b) quality control dept.
   c) quality assurance dept.
   d) none of these.

viii) Good manufacturing practices for pharmaceutical products belongs to
   a) schedule *N* b) schedule *T*
   c) schedule *M* d) schedule *O*.

ix) HEPA filter is used for filtering
   a) heavy viscous solution
   b) sterile solution
   c) air
   d) none of these.

x) Aseptic filling in pharma industry is carried out in
   a) grade *D* area b) grade *A* area
   c) grade *C* area d) grade *B* area.

xi) The usual source of gamma radiation
   a) Cobalt - 60 b) Iodine - 129
   c) Helium - 40 d) None of these.

GROUP – B
(Short Answer Type Questions)

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

2. Write in brief about the general requirements for control of components and drug product containers and closures.

3. What are the factors have to be considered for selection of equipments in pharmaceutical industry.

4. What do you mean by the term 'laboratory control' ? What are the general requirements for laboratory control as per US CGMP ? 1 + 4

5. Give an outline on the selection of an ideal premises and location for a liquid section.

6. Control of contamination is the basis of cGMP. How will you justify ?

GROUP – C
(Long Answer Type Questions)

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

7. What do you mean by the term 'analytical validation' ? Discuss the ICH validation guidelines for analytical validation. Write down the stability testing of drug products as per ICH. Write down the specifications for starting and packaging materials, intermediate and bulk products as well as for finished products. 2 + 6 + 7

8. Discuss in details about the equipment cleaning and maintenance of equipments.

9. What do you understand by the term 'in-process quality control' ? How is the in-process quality control of small volume parenteral preparations carried out in a GMP certified company ? State its importance in Quality Management System. 4 + 8 + 3

10. Define the term 'sterility'. Why is sterility required ? Discuss various methods of sterilization with their sepecific merits and demerits. $2\frac{1}{2} + 2\frac{1}{2} + 10$

11. Discuss in detail about the ventilation, air filtration, air heating and cooling, plumbing, washing and toilet facilities as per subpast *C* of GMP. 5 × 3