Total No. of Questions : 6]

SEAT No. :

P3175

[Total No. of Pages : 3

[5245]-701

Final Year B.Pharmacy (Semester - VII)

STERILE PRODUCTS

(2013 Pattern)

Time : 3 Hours] *[Max. Marks :70*

Instructions to the candidates:

1) ***All questions are compulsory.***
2) ***Answers to two sections should be written in separate answer books.***
3) ***Figures to the right indicate full marks.***
4) ***Draw neat diagrams wherever necessary.***

SECTION - I

Q1) Give an elaborate account of various air class zones in sterile parenteral manufacturing facility. Explain the significance of air class buffering zones, positive pressure and air lock system. **[10]**

OR

Give types of glass and plastics used in packaging of sterile parenteral products. Write an elaborate account of evaluation of rubber closures for vials as per I.P.

Q2) Answer the following (Any five) : **[15]**

a) Describe general requirements for sterile parenteral products.

b) How types I glass is differentiated from type II glass as per I.P.?

c) What are pyrogens? What are the methods to get pyrogen free water?

d) What I.P.Q.C. tests are done on sterile parenteral product before filling and sealing?

e) Describe applications, advantages and disadvantages of sterile parenteral products.

f) Describe factors that decide the choice of container and closure system for a sterile parenteral product.

g) Write note on prefilled syringes.

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Q3) Answer the following (any two) : **[10]**

a) Write note on sterile reconstituted products.

b) Give flow diagram for large scale Manufacture process of aqueous sterile solution having heat stable drug.

c) Write note on stability study of SVPs (Small Volume Parenterals)

d) Enlist official quality control tests for SVPs (Small Volume Parenterals) Describe the test for freedom from particulate matter.

SECTION - II

Q4) Write the ideal properties of plasma volume expanders. Explain different types of plasma volume expanders. **[10]**

OR

Explain in detail types and formulation of LVPs (Large Volume Parenterals)

Q5) Answer the following (any five) : **[15]**

a) Explain the importance of primary drying in lyophilization.

b) What is intra venous admixture?

c) Explain absorbent foam dressings?

d) How will you evaluate ophthalmic products?

e) Write the applications of contact lens.

f) Write the ideal properties of ligatures and sutures.

g) Explain the preparation and storage of dried human plasma.

Q6) Write a note on (any two) : **[10]**

a) Working of lyophilizer

b) Whole human blood

c) Surgical cotton

d) Stability of LVPs (Large Volume Parenterals)

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