

Total No. of Questions : 6]

SEAT No. :

**P2003**

**[5145]-701**

[Total No. of Pages : 2

**F.Y.B.Pharm.**

**STERILE PRODUCTS**

**(2013 Pattern) (Semester - VII)**

*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)** Explain the role of tonicity modifiers and preservatives in the formulation of sterile parenteral products. **[10]**

OR

Explain in details the large scale manufacture of sterile aqueous suspensions.

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

- a) Give principle of working of HEPA and laminar flow.
- b) What are the challenges in development of parenteral formulations containing proteins and peptides.
- c) Write note on various solvents used in formulation of SVPs (small volume parenterals).
- d) Explain working of membrane filters.
- e) Classify SVPs (small volume parenterals) with examples.
- f) Write note on prefilled syringes.
- g) Write note on various routes of parenteral administration with examples of formulations administered by that route.

**P.T.O.**

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

- a) Give importance of solubility analysis as preformulation parameter for development of sterile parenteral formulation.
- b) Explain the principle and process of FFS technology.
- c) Enlist all the quality control tests for SVPs (small volume parenterals) with special note on pyrogen testing. (Bacterial endotoxin test) as per I.P.
- d) Write note on sterile reconstituted products.

**SECTION - II**

**Q4)** Explain in detail different steps involved in freeze drying process. **[10]**

OR

Write an elaborate account of stability aspects of LVPs. Explain the quality control tests for LVPs.

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

- a) Write the ideal properties of plasma volume expanders.
- b) Write different types of primary wound dressing.
- c) Write types of dosage forms for ophthalmic use.
- d) Explain in short quality control of blood products.
- e) Explain in short evaluation tests for ophthalmic products.
- f) Write quality control tests of catgut.
- g) Write the classification of surgical Bandages.

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

- a) Principle of lyophilization and role of cryoprotectants.
- b) Parenteral nutrition.
- c) Contact lens.
- d) Formulation of LVPs.

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