

Total No. of Questions : 6]

SEAT No. :

**P1464**

**[5049]-701**

[Total No. of Pages : 2

**Final Year B.Pharmacy**  
**STERILE PRODUCTS**  
**(2013 Pattern) (Semester - VII)**

*Time : 3 Hours]*

*[Max. Marks : 70*

*Instructions to the candidates:*

- 1) *All questions are compulsory.*
- 2) *Answers to the two Sections should be written in separate answer books.*
- 3) *Figures to the right indicate full marks.*

**SECTION - I**

**Q1)** Explain the role of HVAC system in sterile parenteral manufacturing facility.  
How is HVAC system maintained and validated? **[10]**

OR

Explain in details importance of personnel training and growing process to be followed for working in sterile parenterals manufacturing process.

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

- a) Explain how quality and quantity of excipients can affect safety and efficacy of sterile products?
- b) What are membrane filters and their applications in sterile product manufacture?
- c) Explain in brief terminal moist heat sterilization process in manufacture of sterile parenteral products.
- d) What excipients are needed for sterile aqueous solution formulation? Support the answer with examples of excipients.
- e) What are advantages of glass over plastic as packaging material for sterile products?
- f) Give classification of sterile products as per route of administration. Support the answer with examples.
- g) What are pyrogens? How pyrogens can be eliminated in production of sterile products?

**P.T.O.**

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

- a) Explain what is aseptic technique of manufacture of sterile products?
- b) Give principle of test for sterility for sterile parenteral products.
- c) Give importance of pH - solubility profile as preformulation parameter for the development of sterile parenteral product.
- d) Give comparative account of WFI-water for injection and SWFI-sterile water for injection as vehicles for sterile products.

**SECTION - II**

**Q4)** Explain the principle, working and applications of lyophilizer. **[10]**

OR

Explain general requirements and formulation development of ophthalmic products.

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

- a) Define and classify ophthalmic products.
- b) Write the advantages of freeze drying.
- c) Explain quality control tests for blood products.
- d) Write different types of bandages.
- e) Write the composition and importance of peritoneal dialysis fluid.
- f) Explain collection and storage of whole human blood.
- g) Explain different types of sutures and ligatures.

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

- a) Total Parenteral nutrition.
- b) Dextran.
- c) Formulation of LVPs.
- d) Stabilization of LVPs.

