## Q.P. Code :01381

**[Time: Three Hours]** **[ Marks:70]**

Please check whether you have got the right question paper.

N.B: 1. All questions are compulsory.
2. Figures to the right indicate full marks.

**1.** **a)** Explain in detail Method for sterility testing of a parenteral powder for reconstitution packed in 10 ml. vials **(04)**

**b)** Elaborate on packaging of ophthalmic solutions **(04)**

**OR**

Give formulation aspects of ophthalmic gels.

**c)** i) State four advantages of sustained release systems. **(02)**

ii) Give equation for calculating total dose of drug if it is to be incorporated in a sustained release dosage form **(02)**

**d)** How is shelf life of formulation derived from Arrhenius equation? **(03)**

**2.** **a)** Elaborate on water for injection with respect to its method of preparation (any one), its purity as per I.P and storage conditions. **(04)**

**b)** Cornea forms effective barrier to drug delivery to eye. Explain. **(03)**

**c)** Discuss hydrolytic degradation. Explain approaches to increase shelf life of formulation containing drug susceptible to hydrolysis **(04)**

**OR**

What is oxidative degradation? How can it be arrested?

**3.** **a)** Justify use of rubber closures in packaging of multi dose parenteral products List pharmacopoeial tests for evaluation of rubber closures. **(04)**

**OR**

Elaborate on different grades of glass used in packaging of parenteral. How are glass ampoules tested for sealing integrity?

**b)** Suitability of a drug in sustained release formulation can be predicted based on its physicochemical properties. Justify giving suitable examples. **(04)**

**c)** List salient features of stability study as per ICH guidelines. **(03)**

**(P.T.O)**

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**4.** **a)** Discuss procedure for large scale manufacture of small volume parenteral suspensions. **(04)**

**b)** Comment on evaluation of ophthalmic suspensions **(03)**

**c)** Write short note on diffusion controlled systems **(04)**

**OR**

Explain working principle of reservoir type of sustained release dosage form

**5.** **a)** Discuss formulation and packaging aspects of intravenous infusions **(04)**

**b)** Write protocol for dissolution testing of sustained release tablets **(03)**

**c)** Write a note on packaging material selection for improving stability of sterile formulations **(04)**

**6.** **a)** Explain principle of laminar flow. What are HEPA filters? **(04)**

**b)** Draw flowchart for manufacture of small volume parenterals **(03)**

**c)** Give composition of a multipurpose contact lens solution explaining each component in brief. **(04)**