

Time : 3 Hrs

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.

(3) Draw neat labeled diagram wherever necessary.

1. a) Explain the principle of leaker test. (02)
- b) What is the full form of LAL and enlist two sources of LAL reagent. (02)
- c) Attempt (any two): (04)
- i) Explain the need to add tonicity adjuster and preservatives in an ophthalmic product.
- ii) State the important considerations to be taken into account while formulating an Ophthalmic suspension.
- iii) Discuss the labeling requirements for ophthalmic solutions and suspensions.
- d) State 4 advantages of oral sustained release systems. (02)
- e) Calculate the maintenance dose for a drug to be administered thrice a day having elimination rate constant as 0.156 per hour and loading dose of 25 mg. (02)
- f) Explain the significance of Arrhenius equation in determining the shelf life of pharmaceuticals. (02)
- g) Give any two limitations of Arrhenius Equation. (01)
2. a) Discuss the different vehicles used to formulate Parenteral Preparations. (04)
- b) Write a note on Precorneal Tear film. (03)
- c) Describe the degradation pathway followed by a drug susceptible to Hydrolysis and methods used to overcome it. (04)

OR

Describe oxidative degradation pathway of a drug and methods used to overcome it.

3. a) Write a note on different types and applications of glass used as a packaging material and Explain the hydrolytic resistance test as per IP. (04)

OR

Write a note on Evaluation of Rubber closures.

- b) Discuss in detail the physicochemical properties of drug to be considered for an oral sustained release product. (04)
- c) Give the temperature and humidity conditions for conducting the stability studies as per ICH guidelines for a product to be stored at room temperature. State the advantages of Accelerated stability studies. (03)
- 4. a) Write a note on Freeze drying process used for injectables. (04)
- b) Enlist the Quality control test for ophthalmic ointments and elaborate on evaluation of metal particles in ophthalmic ointment. (03)
- c) Explain Matrix based controlled drug delivery system. (04)

OR

Explain Ion Exchange controlled drug delivery system.

- 5. a) Discuss the formulation aspects of Large volume Parenterals. (04)
- b) Write a note on drug release studies performed on sustained release systems. (03)
- c) Write a note on interaction of parenteral solutions with its primary packaging material. (04)
- 6. a) Give the area classification for sterile products manufacturing. How are HEPA filters tested for integrity? (04)
- b) Elaborate on requirements for personnel working in sterile products manufacturing area. (03)
- c) Enlist various types of contact lenses and elaborate on Contact lens solutions. (04)
