Q.P. Code :01382

[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) i) Elaborate on tests to detect pyrogens **(02)**

ii) List quality control tests for injectable formulations. **(02)**

b) Justify the need for ophthalmic suspensions and elaborate on additives used to formulate them. **(04)**

OR

Elaborate on Preservatives used in ophthalmic products.

c) i) Differentiate between controlled release and sustained release systems. **(02)**

ii) How is the dose calculated for a sustained release formulation? **(02)**

d) State Arrhenius equation and explain its use in predicting shelf-life of pharmaceuticals. **(03)**

2. a) Discuss the composition of small volume parenterals **(04)**

b) Explain permeation of drug through cornea. **(03)**

c) Describe photolytic degradation. How can it be prevented in pharmaceuticals? **(04)**

3. a) Write a note on plastics as a material of packaging for parenteral and enlist QC tests for the same. **(04)**

OR

Discuss QC tests performed on rubber closures.

b) Discuss drug properties to be considered in the design of sustained release products. **(04)**

c) Which are the zones as per ICH Guidelines? Elaborate on the specified testing conditions for accelerated stability studies. **(03)**

4. a) State the principle of Freeze drying. Explain the Freeze drying process for injectables. **(04)**

b) Write a note on particulate matter evaluation in ophthalmic solutions. **(03)**

c) Differentiate between matrix and reservoir based controlled drug delivery systems. **(04)**

OR

Explain dissolution based controlled drug delivery systems.

(P.T.O)

5. **a)** Define large volume parenterals. Explain their formulation aspects. **(04)**

b) Describe evaluation tests for oral-sustained release systems. **(03)**

c) Elaborate on incompatibilities between parenteral solutions and their packaging materials. **(04)**

6 **a)** Define the classes in sterile products manufacturing area. How do you monitor the environment in aseptic area? **(04)**

b) Elaborate on requirements for personnel working in sterile products manufacturing area. **(03)**

c) Enlist various contact lens solutions and describe their composition. **(04)**