

QP Code : 21805

(3 Hours)

[Total Marks : 70

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

1. a) (i) State the principle of Leaker testing. 2
(ii) LAL testing is better than rabbit testing in detection of pyrogens. 2
Justify.
b) Discuss formulation additives and packaging in ophthalmic ointments. 4

OR

Enlist preservatives used in ophthalmic products and state the criteria of passing of preservative efficacy test.

- c) (i) Compare and contrast sustained and controlled release drug delivery system. 2
(ii) How is the total dose calculated in S.R. systems. 2
d) Discuss application of Arrhenius equation in predicting shelf life of pharmaceutical products. 3
2. a) Comment on additives used in the formulation of small volume parenterals. 4
b) Write a short note on ocular bioavailability. 3
c) Discuss oxidative degradation in pharmaceuticals and state the methods to minimize such degradations. 4

OR

Describe the hydrolytic degradation pathway and approaches to prevent it.

3. a) Elaborate on the glass containers in parenterals and discuss tests to distinguish between them. 4

OR

Enumerate the quality control tests done on rubber closures.

- b) Discuss in detail properties of drug to be considered in design of SR system. 4
c) Write in detail on ICH guidelines for accelerated stability studies. 3

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QP Code : 21805

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| 4. | a) | Elaborate principle and steps in Freeze drying of sterile products. | 4 |
| | b) | Write quality control testing of ophthalmic suspensions. | 3 |
| | c) | Discuss dissolution based controlled drug delivery system. | 4 |

OR

Differentiate between matrix and reservoir based controlled drug delivery system.

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| 5. | a) | Discuss the formulation of large volume parenterals. | 4 |
| | b) | Elaborate on evaluation of oral controlled drug delivery system. | 3 |
| | c) | Discuss the form fill seal technology in parenterals. | 4 |
| 6. | a) | Discuss the HEPA filter and laminar air flow. How do you monitor the environment in aseptic area. | 4 |
| | b) | Give the layout for parenteral manufacturing facility. | 3 |
| | c) | State the types of lenses and elaborate on contact lens solution. | 4 |

LO-Con. 7008-15.