

[Time: 2½ Hours]

[Marks:60]

Please check whether you have got the right question paper.

- N.B:**
1. All questions carry equal marks.
 2. Attempt all questions.

- Q.1 Answer the following – any two: (12)
- a) Give the attributes of an ideal cleaning agent and describe detergent ingredients and their properties.
 - b) Describe non- GMP factors and QA functions beyond GMP.
 - c) Discuss the benefits of ISO 9000 quality systems.
 - d) Explain how the cost of quality of medicinal product equates to a contribution to profit.
- Q.2 Discuss the following with respect to pharmaceutical industry – any two: (12)
- a) Types of non-living contaminations.
 - b) Topics for GMP training.
 - c) Measures taken for operator hygiene and health check.
 - d) Types of documentation.
- Q.3 Answer the following – any two: (12)
- a) What are biocide neutralizers? How are they evaluated for their efficacy?
 - b) Write a note on- validation of the preservative efficacy test.
 - c) Chemical and physical characteristics of the cosmetic directly affect preservative efficacy and stability – Justify
 - d) Discuss the various factors that influence the results of assays of preservative efficacy.
- Q.4 Answer the following – any two: (12)
- a) Briefly discuss the Major challenges in natural drug discovery product.
 - b) Write a Note on – Homology modeling of proteins in drug discovery.
 - c) Discuss – Application of proteomics in drug discovery.
 - d) Comment on the importance of HTS in drug development.
- Q.5 Do as Directed: (04)
- (a) Define/ Explain the term – any four
- i. An implantable device
 - ii. Chelating agent
 - iii. Intravenous additives
 - iv. Area cleanliness Class Y
 - v. Membrane active biocide
 - vi. Preservative resistance
 - vii. Target validation
 - viii. BLASTP

(b) Give two examples of – any four

(04)

- i. BPCs
- ii. Chlorine-releasing sanitizers
- iii. Types of autoclave
- iv. Employees who need training
- v. Challenge organisms used for preservative efficacy testing
- vi. Organizations that serve as sources for guidelines for preservation efficacy testing of cosmetics
- vii. Techniques used in protein structure prediction
- viii. Sequence alignment program

(c) State the objective underlying or the significance of – any two

(04)

- i. Suitable working conditions in any organization
- ii. Excipients in sterile injections
- iii. Re-challenge tests of cosmetics
- iv. 2D-PAGE in proteomics