

Total No. of Questions : 5]

SEAT No. :

PF-12141

[Total No. of Pages : 2

[6648]-845

S.Y. M.B.A.

**SE-PHM 14 : QUALITY ASSURANCE AND CONTROL
MANAGEMENT IN PHARMA
(2024 Pattern) (Semester - IV)**

Time : 2½ Hours]

[Max. Marks : 50

Instructions to the candidates :

- 1) All questions are compulsory.
- 2) Each question has internal options.
- 3) Each question carries equal marks.

Q1) Attempt Any Five out of eight following questions :

[5 × 2 = 10]

- a) Define Quality and explain its dimensions.
- b) Differentiate between Quality Assurance (QA) and Quality Control (QC).
- c) State any four principles of Quality Management in pharmaceuticals.
- d) What are the responsibilities of the Quality Assurance department?
- e) Define Good Laboratory Practices (GLP).
- f) What is Quality Risk Management?
- g) Define Standard Operating Procedure (SOP).
- h) State any two regulatory agencies governing pharmaceutical quality.

Q2) Attempt any two out of three from the following :

[2 × 5 = 10]

- a) Importance of Quality Audits in the pharmaceutical industry.
- b) Raw material control and in-process quality control techniques.
- c) Quality documentation and batch record management.

P.T.O.

Q3) a) Explain Current Good Manufacturing Practices (CGMP) and their role in ensuring product quality and safety. **[10]**

OR

b) Discuss the process of Quality Assurance Management and list analytical techniques used in Quality Control. **[10]**

Q4) a) Explain QA principles in drug development phases (preclinical and clinical). Also discuss GCP guidelines and patient safety. **[10]**

OR

b) Discuss data integrity, ethical considerations and regulatory compliance in clinical trials. **[10]**

Q5) a) Explain modern quality tools such as Kaizen, Six Sigma, Lean, JIT and 5S. How do they help in process optimization? **[10]**

OR

b) Discuss the impact of digital technologies (AI, IoT, Data Analytics) and emerging trends such as personalized medicine and biopharmaceuticals in pharmaceutical quality management. **[10]**

