

Enrollment No: _____ Exam Seat No: _____

C.U. SHAH UNIVERSITY

Winter Examination-2022

Subject Name: Quality Management System

Subject Code: MQA102T

Semester: 1

Date: 14/03/2023

Branch: M.Pharm (PQA)

Time:10:30 To 01:30

Marks: 75

Instructions:

- (1) Use of Programmable calculator & any other electronic instrument is prohibited.
- (2) Instructions written on main answer book are strictly to be obeyed.
- (3) Draw neat diagrams and figures (if necessary) at right places.
- (4) Assume suitable data if needed.

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- Q-1 Attempt the following questions: (20)**
- a) Define Quality 2
 - b) Give importance of OSHAS guideline. 2
 - c) Explain Risk Assessment. 2
 - d) What do you mean by Process Control? 2
 - e) Give the functions of IPQC. 2
 - f) Write the concept of TQM. 2
 - g) Differentiate OOS and OOT. Give importance. 2
 - h) Define CAPA. 2
 - i) Define HACCP 2
 - j) Enumerate the section of ICH guidelines for Drug stability. 2
- Q-2 Attempt any two of following : (20)**
- a) Elaborate Statistical Process control (SPC), Give definition and importance , General aspects and advantages of statistical control. 10
 - b) Explain basics of Quality Management. Write a brief on ICH Q10. 10
 - c) Give a brief on WHO GMP requirement for Quality Management System. 10
- Q-3 Attempt any Seven of following : (35)**
- a) Explain Strategy and Strategy management in brief. 5
 - b) Explain ISO 14001:2004 in detail. 5
 - c) Give a brief on ICH Q9 guideline 5
 - d) Define Benchmarking. Explain its types along with limitation. Describe process of NABL certification 5
 - e) Give the principles of SIX Sigma. 5
 - f) Write a brief note on McKinsey's 7S Model 5
 - g) Define Quality by Design along with its concept & advantages 5
 - h) Explain concept of "Cost of Quality" with category and model. 5
 - i) Explain the process of evaluation, handling, Investigation and determination of Root cause. 5

