

Your Roll No.....

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School of Pharmaceutical Education and Research
M. Pharm. I Semester Examination (2023-24)

Subject: **Quality Management Systems**
Paper Code: **MQA102T**

Date: **11-3-2024**

Maximum Marks: **75**
Time: **Three hours**

(Write your Roll No. on the top immediately on receipt of this question paper)

Note: This paper has two Sections; A and B.
Attempt all the two sections.
Section A: Answer all the questions.
Section B: Answer any 4 out of 6 questions

Abbreviations Used:

CO- Course Outcome, PO- Program Outcome, BTL- Bloom Taxonomy Level: BT level 1- Remember; BT level 2- Understand; BT level 3- Apply; BT level 4- Analyze; BT level 5- Evaluate; BT level 6- Create.

SECTION-A

Answer the following in brief (Attempt all questions)

5x3= 15 Marks

Q. No 1	Question	BTL	CO	PO
(a)	How will you define "Quality"?	1	3	1, 2
(b)	Distinguish between Quality Control and Quality Assurance.	1	3	1, 3
(c)	What are the types of customer (any four)?	1	3	1
(d)	Differentiate between Out of Specifications (OOS) and Out of Trend (OOT)	1	3	3
(e)	Elaborate on the concept of Recalls	2	2	1, 8

SECTION B

Long type Questions (Attempt any 4 out of 6)

4x15= 60 Marks

	Question	BTL	CO	PO
Q. No 2	Explain McKinsey's 7 S Model.	2	2	1
Q. No 3	Discuss various dimensions of Quality.	3	3	1, 2
Q. No 4	Explain the concept of Statistical Process Control.	2	4	8
Q. No 5	What are the principles of Six sigma?	1	3	3
Q. No 6	Give reasons for benchmarking. Mention the types, advantages and disadvantages of benchmarking.	2	1, 2, 4	1
Q. No 7	ICH guidelines for stability testing of drug substances and drug products.	5	2, 4,	2