

C.U.SHAH UNIVERSITY

Winter Examination-2020

Subject Name : Quality Management System

Subject Code : MQA102T

Branch: M.Pharm (Quality Assurance)

Semester: 1

Date: 09/03/2021

Time: 11:00 To 02:00

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.

Q-1	Attempt the following questions:	(20)
	a) Discuss in brief about HACCP.	2
	b) Write in brief about returns and recalls.	2
	c) What is vendor qualification?	2
	d) Discuss in brief about CAPA.	2
	e) What do you mean by TQM?	2
	f) What do you mean by process capability?	2
	g) Classify customers.	2
	h) What do you mean by CFR-21 part 11?	2
	i) What is concept of self inspection?	2
	j) What is concept of IPQC?	2

Attempt the following questions:

Q-2	Attempt any two of following :	(20)
A	Define Benchmarking. Write in detail about types and process of benchmarking.	10
B	Write a detailed note on quality by design and process development report.	10
C	What do you mean by six sigma? Discuss in detail about principles of six sigma.	10

Q-3	Attempt any Seven of following :	(35)
A	Share your detailed knowledge on Mc Kinsey 7s model.	5
B	What do you mean by customer? Discuss about factors affecting customer perception.	5
C	What do you mean by SPC? Discuss importance of SPC.	5
D	Discuss in detail about batch review and batch release.	5
E	Discuss about OOS and OOT.	5
F	Discuss about NABL accreditation.	5
G	What do you mean by risk? Discuss about risk assessment and risk control.	5
H	Discuss about statistical control charts.	5
I	Discuss in detail about quality management system.	5

