C.U. SHAH UNIVERSITY
Winter Examination-2019

Subject Name: Quality Management System
Subject Code: MQA102T   **Branch: M.Pharm (QA)**
Semester: 1   Date: 03/12/2019   Time: 02:30 To 05:30   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.

Q-1		Attempt the following questions:	(20)
	a)	Define the term Drug stability with example?	**2**
	b)	Give importance of OSHAS Guideline.	**2**
	c)	Explain Risk Management Tools.	**2**
	d)	What do you mean by Process Control?	**2**
	e)	Discuss about Dimensions of Quality.	**2**
	f)	Write the Concept of TQM.	**2**
	g)	Give Brief note on OOS and OOT	**2**
	h)	Define CAPA.	**2**
	i)	What do you mean by Line Clearance.	**2**
	j)	Give Importance of ISO marking.	**2**

Attempt the following questions:

Q-2		Attempt any two of following :	(20)
	A	Discuss WHO GMP guideline for Quality Management System.	**10**
	B	Brief note on ICH Guidelines for Stability Testing of Drug Product & Drug Substances (Q8).	**10**
	C	Define: Statistical control charts. Discuss its concept along with its advantages in pharma field.	**10**

Q-3		Attempt any Seven of following :	(35)
	A	Give the Principles of SIX Sigma.	**5**
	B	Explain ISO 14001:2004 in detail.	**5**
	C	Define Benchmarking, Explain its types along with limitation.	**5**
	D	Explain process of Batch review and batch release.	**5**
	E	Briefly explain Conept of IPQC	**5**
	F	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	Describe process of NABL certification.	**5**