Enrollment No: _____ Exam Seat No: _____

C.U.SHAH UNIVERSITY

Summer Examination-2017

Subject Name: Total Quality Management & Documentation

Subject Code: 5PS02TQM2 **Branch: M.Pharm (QA)**

Semester: 2 **Date: 09/05/2017** **Time: 02:00 To 05:00** **Marks: 70**

Instructions:

(1) Use of Programmable calculator and 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.

SECTION – I

Q-1 **Define the following terms:** **(07)**

a. Quality **1**
b. Customer **1**
c. Leadership **1**
d. Production planning **1**
e. Cross-contamination **1**
f. Teamwork **1**
g. Stability **1**

Q-2 **Attempt all questions** **(14)**

(a) Discuss the concept of quality as per Juran. **7**
(b) Write concepts and principles of TQM regarding Customer. **7**

OR

Q-2 **Attempt all questions** **(14)**

(a) Discuss the concept of quality as per Shikawa. **7**
(b) Write concepts and principles of TQM regarding Leadership and teamwork. **7**

Q-3 **Attempt all questions** **(14)**

(a) Write a note on bar graphs as quality tools for TQM. **7**
(b) Describe ISO 9000 series. **7**

OR

Q-3 **Attempt all questions**

(a) Discuss on scatter diagram as quality tools for TQM. **7**
(b) Describe in-process quality control of tablets. **7**

SECTION – II

Q-4		**Write the full form of following terms:**	**(07)**
	a.	CAPA	**1**
	b.	ISO	**1**
	c.	cGMP	**1**
	d.	ISI	**1**
	e.	PAT	**1**
	f.	ICH	**1**
	g.	NDA	**1**
Q-5		**Attempt all questions**	**(14)**
	(a)	Describe in-process quality control of parenterals.	**7**
	(b)	What is TGA ? Discuss TGA's risk management approach.	**7**
		OR	
Q-5		**Attempt all questions**	**(14)**
	(a)	Discuss role of CBER in USFDA.	**7**
	(b)	Discuss Supplemental New Drug Application with recent examples.	**7**
Q-6		**Attempt all questions**	**(14)**
	(a)	Differentiate between NDA and ANDA. Explain the concept of PARA I to IV filing.	**7**
	(b)	Write a note on effluent treatment plant.	**7**
		OR	
Q-6		**Write notes on:**	**(14)**
	(a)	Stability testing guideline as per ICH for pharmaceutical drug product.	**7**
	(b)	QbD.	**7**