Exam Seat No:_____ Enrollment No:_____

C.U.SHAH UNIVERSITY

Wadhwan City

Subject Code : 5PS02TQM1 **Summer Examination-2014** **Date: 30/06/2014**

Subject Name: Total Quality Management & Documentation

Branch/Semester:- M.Pharm /II **Time:2:00 To 5:00**

Examination: Regular

Instructions:-

(1) Attempt all Questions of both sections in same answer book / Supplementary

(2) Use of Programmable calculator & any other electronic instrument is prohibited.

(3) Instructions written on main answer Book are strictly to be obeyed.

(4) Draw neat diagrams & figures (If necessary) at right places

(5) Assume suitable & Perfect data if needed

SECTION-I

Q.1	Attempt the Following	1X7=7
i.	Define TQM.	
ii.	What are the six basic concepts that a successful TQM Programme requires?	
iii.	Give the Principles of TQM?	
iv.	Give the Obstacles or Barriers associated with TQM Implementation?	
v	What do you mean by Quality Circles?	
vi	Define Cause and Effect Diagram?	
vii	Scope of Total Quality Management (TQM)	
Q.2 (a)	Enlist fourteen points of Deming's for quality management.	5
(b)	Write note on Juran's Quality Trilogy	5
©	Write note on The Kano Model of Customer Satisfaction	4
	OR	
(a)	Elaborate Cause and Effect Diagram.	5
(b)	Write purpose and benefit of flow chart in quality tools.	5
(c)	Write purpose and benefit of Histogram in quality tools.	4
Q.3 (a)	Write principles of ISO	7
(b)	Write in Process quality controls on Tablets dosage forms.	7
	OR	
(a)	Discuss design of effluent treatment plant	7
(b)	Write short notes on MSDS.	7
Q.4	Attempt the Following	1X7=7
I.	Define ISO 9000.	
ii.	Write Objective of ISO	
iii.	Enlist Principles of ISO	
iv.	Discuss requirement of ISO 9001-2000	
v.	Write the step of ISO registration	
vi.	What is QTPP?	
vii.	What is PAT?	
Q.5 (a)	Write short note on common technical documents.	5
(b)	Add note on Out of Specification.	5
(c)	Write brief note on Site master file.	4
	OR	
(a)	Write note on ISI	5
(b)	Write note on UK-MCA.	5

(c)	Write short note on WHO.	4
Q.6 (a)	Discuss Preparation of documents for New Drug Application (NDA) as per requirements of FDA guidelines.	7
(b)	Discuss Various elements of QBD.	7
	OR	
(a)	Why is risk assessment required in product development?	7
(b)	Discuss QBD for Immediate-Release Dosage Forms.	7

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