Exam Seat No:_____ **Enrollment No:_____**

C.U.SHAH UNIVERSITY
WADHWAN CITY
University (Winter) Examination -2013

Course Name :M.Pharm Sem-I **Subject Name: -Quality Assurance Technique** **Duration :- 3:00 Hours**
Date : 13/1/2014 **Marks : 70**

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 Explain the following term **07**

I. Quality Risk Management

II. State of Control

III. Change Management

IV. Control Strategy

V. Design Space

VI. Product Realisation

VII. Quality Planning

Q.2 (a) Write short notes on quality risk management **05**
(b) Write general guidelines given for personnel selection and training **05**
(c) Discuss the objectives of ICH Q10. **04**

OR

Q.2 (a) Write a note on cleaning, sanitization & sterilization of equipment. **05**
(b) Discuss various criteria for raw materials purchase specification. **05**
(c) Write down definition and objective of SOP **04**

Q.3 (a) Define and classify quality audit. Discuss internal audit in brief. **07**
(b) Write short note on MFR. **07**

OR

Q.3 (a) Discuss the guidelines for handling of raw materials as per GMP and WHO. **07**
(b) What is importance of Line Clearing? describe how is it practised during Production and packing process? **07**

SECTION – II

Q.4 Explain the following term **07**

I. Test facility

II. Principal investigator

III. Study completion date

IV. Quality review

V. Self inspection

VI. CAPA

VII. Knowledge Management

13-14

Q.5	(a)	Discuss design construction and maintenance of ware house	**05**
	(b)	Write an account of Good Distribution Practices	**05**
	(c)	What is recall strategy? Describe the recall procedure.	**04**

OR

Q.5	(a)	Describe waste and scrap disposal procedures.	**05**
	(b)	Write in brief about study plan and performance of study.	**05**
	(c)	Write an account of Good Documentation Practices	**04**

Q.6	(a)	Discuss about the Tests used for printed packing materials, glass bottles & Vials	**07**
	(b)	Write note on GLP	**07**

OR

Q.6			
	(a)	Write specifications generally employed for Drug Substance & drug Products	**07**
	(b)	Describe GMP guidelines for quality control laboratory.	**07**

*******13**14********