Exam Seat No:	Enrollment No:
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## C.U.SHAH UNIVERSITY WADHWAN CITY

## **University (Winter) Examination -2013**

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

**Instructions:-**

1)	Attempt all	Ouestions	of both	sections	in same	answer	book /	Supplementary	V.

- (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.

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	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	
(a) (b) (c)	Write short notes on quality risk management Write general guidelines given for personnel selection and training Discuss the objectives of ICH Q10.	05 05 04
(a) (b) (c)	Write a note on cleaning, sanitization & sterilization of equipment.  Discuss various criteria for raw materials purchase specification.  Write down definition and objective of SOP	05 05 04
(a) (b)	Define and classify quality audit. Discuss internal audit in brief. Write short note on MFR.	07 07
(a)	Discuss the guidelines for handling of raw materials as per GMP and	07
(b)	What is importance of Line Clearing? describe how is it practised during Production and packing process?	07
I.	Explain the following term Test facility	07
II.	Principal investigator	
III.	Study completion date	
IV.	Quality review	
V.	Self inspection	
VI.	CAPA	
VII.	Knowledge Management	
	II. IV. V. VI. VII. (a) (b) (c) (a) (b) (iii) II. III. IV. V. VI.	I. Quality Risk Management  II. State of Control  III. Change Management  IV. Control Strategy  V. Design Space  VI. Product Realisation  VII. Quality Planning  (a) Write short notes on quality risk management  (b) Write general guidelines given for personnel selection and training  (c) Discuss the objectives of ICH Q10  (a) Write a note on cleaning, sanitization & sterilization of equipment.  (b) Discuss various criteria for raw materials purchase specification.  (c) Write down definition and objective of SOP  (a) Define and classify quality audit. Discuss internal audit in brief.  (b) Write short note on MFR.  OR  (a) Discuss the guidelines for handling of raw materials as per GMP and WHO.  (b) What is importance of Line Clearing? describe how is it practised during Production and packing process?  SECTION – II  Explain the following term  I. Test facility  II. Principal investigator  III. Study completion date  IV. Quality review  V. Self inspection  VI. CAPA

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
<b>Q.6</b>	(a)	Discuss about the Tests used for printed packing materials, glass bottles & Vials	07
	(b)	Write note on GLP	07
	(0)	OR	0,
Q.6			
Q.	(a)	Write specifications generally employed for Drug Substance & drug Products	07
	(b)	Describe GMP guidelines for quality control laboratory.	07

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