

GUJARAT TECHNOLOGICAL UNIVERSITY**M.PHARM - SEMESTER-II • EXAMINATION – SUMMER-2016****Subject Code: 2920208****Date: 21/05/2016****Subject Name: INDUSTRIAL PHARMACY - IV****Time: 10:30 AM To 1:30 PM****Total Marks: 80****Instructions:**

1. Attempt any five questions.
2. Make suitable assumptions wherever necessary.
3. Figures to the right indicate full marks.

Q.1	(a) Give the general description of GLP.	06
	(b) Define ISO and give brief note on ISO 9000.	05
	(c) Give the requirement of cGMP.	05
Q.2	(a) Differentiate accuracy and precision.	06
	(b) Give the concepts of good clinical practice.	05
	(c) Write note on EMEA implementation of new EU Pharma. Legislation.	05
Q.3	(a) Define CTD and eCTD. Give technical requirement for eCTD.	06
	(b) Write note on ANVISA.	05
	(c) Discuss the TGA's risk management approach.	05
Q.4	(a) Discuss the WHO certification scheme for pharmaceutical product.	06
	(b) Explain scope of USFDA regulation and discuss preparation required for USFAD audit.	05
	(c) Write note on MHRA.	05
Q.5	(a) Define CIP and SIP system. Explain cleaning validation parameters.	06
	(b) Write note on validation of dry heat sterilizer.	05
	(c) Differentiate prospective and retrospective validation.	05
Q. 6	(a) Explain IIG.	06
	(b) Write note on CDER.	05
	(c) What is ERP? Give merits and demerits of ERP.	05
Q.7	(a) Categorize ICH activities and write note on evaluation of stability data.	06
	(b) Give importance of orange book and explain statistical criteria for bioequivalence.	05
	(c) Write note on quality audited.	05
