Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

M.PHARM- SEM-II–EXAMINATION – JULY 2012

Subject code: 2920202 Date: 09/07/2012

Subject Name: Global Regulatory Requirements

Time: 10:30 am – 01:30 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)	Define Process Validation and explain its importance in Pharmaceutical Industry. Write a note on Revalidation.	**06**
	(b)	Give full form for following abbreviations: (i) SMF (ii) ERP (iii) QbD (iv) CTD (v) ICH (vi) SUPAC (vii) ARTG (viii) MCC (ix) MCA and (x) ANVISA	**05**
	(c)	Discuss different plans of USFDA.	**05**
Q.2	(a)	Discuss in detail Retrospective Validation.	**06**
	(b)	Enlist the different sections of NDA and explain CANDA.	**05**
	(c)	Discuss the risk management approach for regulating medicines supplied in Australia in context to TGA.	**05**
Q.3	(a)	Mention the purposes of equipment validation. Explain the four elements of the same.	**06**
	(b)	State the goals of NDA. Prepare a NDA chart showing NDA review process.	**05**
	(c)	Write a note on IIG.	**05**
Q.4	(a)	Write a note on MHRA.	**06**
	(b)	Write a note on Validation Protocol.	**05**
	(c)	Explain the concept of ANDA and prepare the flow chart showing ANDA review process.	**05**
Q.5	(a)	Mention various processing stages and process critical parameters in context to process validation of Tablet Manufacturing Process.	**06**
	(b)	Discuss in detail Type II DFM.	**05**
	(c)	Discuss the historical aspects of drug development and its approval.	**05**
Q. 6	(a)	Mention three broad areas of information that IND application must contain and enlist Guidance documents to help prepare INDs.	**06**
	(b)	Write the purpose of Computer System Validation. Discuss DQ and IQ in the said context.	**05**
	(c)	Define Drug Master File, Holder, Agent and Application and differentiate between Applications and DMFs.	**05**
Q.7	(a)	Enlist the basic criteria for new analytical method development for dosage forms and enumerate various analytical methods in this context. Mention the advantages of HPLC method.	**06**
	(b)	Discuss the phases of investigation in context to IND.	**05**
	(c)	Define Orange book and explain the need of the same. Define various therapeutic equivalence related terms in context to the same.	**05**

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