Seat No.: _____ Enrolment No._____

GUJARAT TECHNOLOGICAL UNIVERSITY

B. Pharm. – SEMESTER – VIII • EXAMINATION – WINTER • 2016

Subject Code: 2280011 Date: 02-12-2016

Subject Name: Drug Approval Process

Time: 02:30 pm - 05:30 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)**	Describe procedure for new drug approval from CDSCO in India	**06**
	(b)	Write note on Freedom of Information.	**05**
	(c)	Describe in detail about concept of Bio similarity.	**05**
Q.2	**(a)**	Explain the following briefly: 1. ANVISA 2. MCA	**06**
	(b)	Write detail about Common Technical Document.	**05**
	(c)	Write short note on Scale Up And Post Approval Changes-IR (SUPAC-IR).	**05**
Q.3	**(a)**	Define and Explain NDA.	**06**
	(b)	Enumerate different type of IND and explain it in detail.	**05**
	(c)	Describe various activity regulated by TGA.	**05**
Q.4	**(a)**	Write concepts of para I to IV filing.	**06**
	(b)	Describe in detail ANDA.	**05**
	(c)	Write short note on USFDA.	**05**
Q.5	**(a)**	What is Drug Master File? Explain various types of Drug Master File.	**06**
	(b)	Give overview on Inactive Ingredient Guide.	**05**
	(c)	Wrote note on Purple Book.	**05**
Q. 6	**(a)**	Briefly introduce MHRA regulatory agencies.	**06**
	(b)	Write short note on ICH.	**05**
	(c)	Explain special emphasis on approval of drug under 505 (b) (2).	**05**
Q.7	**(a)**	Explain in detail WHO guideline.	**06**
	(b)	Write detail note on SUPAC-MR.	**05**
	(c)	Write briefly on orange book.	**05**

****