

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY
B. Pharm. – SEMESTER – VIII • EXAMINATION – WINTER • 2016

Subject Code: 2280011
Subject Name: Drug Approval Process
Time: 02:30 pm - 05:30 pm

Date: 02-12-2016
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)	Write 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
