

Seat No.: _____

Enrolment No. _____

GUJARAT TECHNOLOGICAL UNIVERSITY
B.PHARM - SEMESTER- 8 EXAMINATION – SUMMER -2019

Subject Code: 2280011

Date: 18-05-2019

Subject Name: Drug Approval Process

Time: 10:30 AM TO 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)	Discuss various phases of drug development and approval.	06
	(b)	Write overview about Inactive Ingredient Guide.	05
	(c)	Write about ANVISA regulatory agency.	05
Q.2	(a)	Discuss brief introductions on WHO and USFDA.	06
	(b)	Write down on Drug Master File.	05
	(c)	Write about concept of bio-similarity.	05
Q.3	(a)	Write a note on Drug Approval in India.	06
	(b)	Write a note on ICH.	05
	(c)	Write short note on Scale Up And Post Approval Changes-MR.	05
Q.4	(a)	Write a note on drug approval process in biopharmaceuticals.	06
	(b)	Explain in brief about SUPAC-IR.	05
	(c)	Explain special emphasis on approval of drug under 505 (b) (2).	05
Q.5	(a)	Explain about the concept of para I to IV in drug approval process.	06
	(b)	Write a note on Abbreviated New Drug Application.	05
	(c)	Explain TGA. Give the structure of TGA.	05
Q. 6	(a)	Write a details note of INDA and NDA.	06
	(b)	Briefly introduce MCA regulatory agencies.	05
	(c)	Write a note on Freedom of information.	05
Q.7	(a)	Write about Common Technical Document in Drug Approval Process.	06
	(b)	Discuss guidelines from CDSCO.	05
	(c)	Write a note on Orange book.	05
