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**

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