

GUJARAT TECHNOLOGICAL UNIVERSITY

B.Pharm
SEMESTER: VIII

Subject Name: Drug Approval Process

Subject Code: 2280011

Teaching Scheme				Evaluation Scheme			
Theory	Tutorial	Practical	Total	Theory		Practical	
				External	Internal	External	Internal
3	0	0	3	80	20	0	0

Sr No	Course Content	Teaching hrs
1.	Basics in drug approval process: Various phases of drug development and approval including clinical and nonclinical development.	3
2.	Overview on: Orange book, Freedom of information, Inactive Ingredient Guide and Drug Master File.	7
3.	Types of Approval: IND, NDA and ANDA. Content, format and application. Concept of para I to IV and generic exclusivity. Special emphasis on approval under 505 (b) (2).	10
4.	Drug Approval in India: Requirements and guidelines from CDSCO.	4
5.	Drug Approval in Developed Countries and Rest of World (Row) markets: Common Technical Document (CTD) and brief introduction to various regulatory agencies like USFDA, MCA, TGA, MHRA, ANVISA, WHO and ICH.	14
6.	Scale Up and Post Approval Changes (SUPAC) guidance: SUPAC-IR, MR and SS.	4
7.	Approval of Biopharmaceuticals: Difference from drug approval and concept of bio-similarity.	3

References Books:

1. The guidance documents shall be procured from the website of the respective government