GUJARAT TECHNOLOGICAL UNIVERSITY

M.Pharm

INDUSTRIAL PHARMACY

SEMESTER: I

SUBJECT NAME: INTELLECTUAL PROPERTY RIGHTS
Subject Code: MIP104T

SCOPE: This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in drug regulatory affairs.

OBJECTIVES: Upon completion of the course, student shall be able to understand

1. Assist in Regulatory Audit process
2. Establish regulatory guidelines for drug and drug products
3. The Regulatory requirements for contract research organization.

Sr.No	Course content	Total Hrs
1.	Definition, Need for patenting, Types of Patents, Conditions to be satisfied by an invention to be patentable, Introduction to patent search. Parts of patents. Filling of patents. The essential elements of patent; Guidelines for preparation of laboratory note book, Non-obviousness in Patent	12
2.	Role of GATT, TRIPS, and WIPO	12
3.	Brief introduction to Trademark protection and WHO Patents. IPR's and its types, Major bodies regulating Indian Pharmaceutical sector	12
4.	Brief introduction to CDSCO. WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA	12
5.	Regulatory requirements for contract research organization. Regulations for Biosimilars	12

REFERENCES:

1. Pharmaceutical Process Validation: By Fra R. Berry and Robert A. Nash, Vol 57, 2nd Edition
2. Applied Production and Operation Management By Evans, Anderson and Williams
3. GMP for pharmaceuticals Material Management by K.K. Ahuja Published by CBS publishers
4. ISO 9000-Norms and explanations
5. GMP for pharmaceuticals- Willing S.H. Marcel and Dekker