

**“STUDY ON IMPURITY PROFILING AND CHARACTERIZATION OF
MAJOR DEGRADATION PRODUCTS FOR SELECTED ANTI-
TUBERCULOSIS DRUGS”**

ABSTRACT

The bacterial disease Tuberculosis (TB) is a two or three-decade-old disease that kills worldwide a number of people every year. In recent years new anti-TB molecules were approved by FDA and CDSCO (India) therefore the anti-TB antibiotics that were not studied were selected and thoroughly analyzed. The three-generation anti-TB drugs were selected; Terizidone (approved by CDSCO in 1981), Rifabutin (approved by CDSCO in 2007) and Bedaquiline (approved by CDSCO in 2015). All these three drugs after the confirmation of identification tests, HPLC methods were developed for each drug separately for the stability study. The Stability study was completed using ICH stability (Q1) and quality Q2 (R1) guidelines and stability of each drug in different conditions were established. Wherever it was possible the degradation products peaks were maximum separated from drug peak in HPLC and major degradation product was identified, isolated and characterized while other minor degradation products were identified based on sophisticated instrument response. Compiling all the data, the proposed degradation pathway was generated for each condition of three drugs. Degradation kinetic study was performed to know the order of reaction and drug response in different media, temperature and at different time using conventional kinetic study method for these drugs. Different kinetic parameters were calculated such as rate constant, half life, shelf life, activation energy, entropy and enthalpy of reaction system. The Design of Experiment approach was used to predict the degradation kinetic parameters of bedaquiline and rifabutin in different conditions to reduce the utilization of solvent and time used during kinetic study. The approach was successfully applied and prediction was compared with the data obtained by conventional kinetic study. The impurity profile was created for all three anti-TB drugs.

Research Scholar

Ms. Pragati J Vanavi

Research Guide

Prof. (Mrs.) Sadhana J Rajput

Faculty of Pharmacy