2. Aims and Objectives

Aim:

Aim of work undertaken was to identify possible impurities and characterize major degradation products of selected Anti tuberculosis drugs. (Terizidone, Bedaquiline and Rifabutin)

Objectives:

Main objectives of present studies were:

- To develop the analytical methods (UV and RP-HPLC) for primary study of selected drugs viz. Terizidone(TRZ), Bedaquiline (BDQ) and rifabutin and validation of developed methods according to ICH quality guidelines.
- To perform stability study using the developed analytical methods for degradation of Active pharmaceutical Ingredients (APIs) and finished dosage form or synthetic mixture for the three selected drugs; TRZ, BDQ and rifabutin as per ICH quality guidelines.
- To study drug degradation kinetics study of selected drug degradation procedures (TRZ, BDQ and rifabutin) by Conventional method.
- To apply Quality by Design (QbD) approach to study the degradation kinetics of selected degradation procedures for BDQ and rifabutin for the prediction of different degradation kinetic parameters.
- To isolate major DPs by suitable isolation method for TRZ, BDQ and rifabutin.
- TO Identify and to Characterize the major DPs by Nuclear Magnetic Resonance (NMR) and/or Tandem MS, Ultra Performance Liquid chromatography- Mass spectroscopy (UPLC-MS) and IR.
- To propose degradation pathway and prepare Impurity profile of process related, inherent and degradation impurities present in three selected drugs TRZ, BDQ and rifabutin.