AIMS AND OBJECTIVES

AIM:

The aim of the work undertaken was to identify the possible impurities and degradation products present in selected drugs (Pidotimod, Edaravone and Ciclopirox Olamine)

OBJECTIVES:

The objectives of the present work include:

- To identify process related or inherent impurity in active pharmaceutical ingredient (API).
- To carryout stress degradation study of selected drugs as per ICH guidelines to check the stability of API.
- To carryout stress degradation study in finished pharmaceutical product (FPP) to identify impurities or degradation product generated by drug-excipient interaction.
- To apply QbD approach for development and validation of specific method for identification and/or quantification of the process related and/or degradation related impurities in selected drugs.
- To study degradation kinetics of selected drugs.
- To isolate major degradation related impurities by conventional or hyphenated techniques.
- To characterize major degradation related impurities by spectroscopic methods like IR, NMR, and Mass.
- To postulate and propose degradation pathway.