

Objective of the thesis

The impurity profiling is available in the literature for several old drugs which are approved a decade or two before to a certain extent but not to the fullest extent. The extent of work on the impurity profiling of the recently approved drugs is very limited and references are hard to find. The innovator or the brand company who submits the NDA (New drug application) shall provide partial impurity profiling information on the drugs submitted. However, when it is manufactured by other generic companies they tend to use different synthetic routes, which will lead to different impurity profiles. Therefore, it is very much in the best interest of the humans who consume these drugs and of the companies who plan to develop the recently approved drugs to know upfront the type of the impurity they should expect and what are the toxicological profiles of those impurities, if they are at or above the threshold levels as guided by the world regulatory bodies like ICH (International Conference on Harmonization) and WHO (World Health Organization).

The present thesis is aimed at understanding the impurity profiles and the most likely degradation pathways possible for the recently approved drugs. The focus is fully on all the possible impurities like organic, inorganic and enantiomeric impurities along with the residual solvent impurities which could generate as part of the degradation pathways. The polymorphic and the particle size impurities are not considered in the present thesis.

Also, the present work focuses upon the structure elucidation and characterization of the impurities in all the selected drugs and development of the stability indicating Analytical methods using sophisticated instruments like LC-MS/MS (Liquid chromatography/Mass spectrometer), NMR (Nuclear Magnetic Resonance), HPLC (High performance Liquid chromatography), preparatory and flash HPLC, Column Chromatography etc.