ABSTRACT

Presence of impurities and degradation products in drugs poses huge risk to patients' health. This is even worsening effects if the drugs are anticancer categories as in such cases the chances of impurities and degradation products to be carcinogenic or genotoxic are very high. Hence to control the impurities and degradation products, various regulatory agencies put great emphasis on identification, characterization and generation of specification limit for control of impurities and other degradation products which are possible to generate in excessive storage conditions.

In present work, three anticancer category drugs were chosen as alectinib, nelarabine and gimeracil. Stability indicating analytical methods was developed for each of these drugs for their estimation by HPLC in presence of their degradation products. To identify the degradation products, detailed forced degradation studies were carried out in the degradation conditions of acid, alkali, oxidative, heat, UV and light. The some major degradation products were isolated using preparative HPLC and then characterized them using various characterization instrument techniques such as NMR, FT-IR, LC-MS/MS and HRMS.