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(57) Abstract :
The present invention relates to a forced degradation is a degradation of new drug substance and drug product at conditions more severe than accelerated conditions. The present invention aims to develop and validate an LC-MS/MS method for precise quantification of degradation products formed during forced degradation studies for Raltegravir. Discloses methods to isolate the major degradation product formed during the forced degradation study and elucidate the structure based on HR MS analysis. The standard solution of Raltegravir was subjected to various stress conditions for 48hrs at room temperature. Then the samples were collected and analysed utilizing the optimized RP-HPLC conditions. A total of seven degradation products formed during various stress studies were isolated, elucidated for the plausible structures. Fig. 1

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