Identification and Separation of the Degradation Products of Vildagliptin Tablets and Raw Material using LC-MS and NMR, and then Exploration of the Corresponding Degradation Pathways

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DOI: https://doi.org/10.35516/jjps.v16i2.1535

ABSTRACT

A gradient high performance liquid chromatography (HPLC) method has been developed for the qualitative and quantitative analyses of vildagliptin related substances. This method is based on using of RP-C18 (250 × 4.6 mm×5µm) and gradient elution with phosphate buffer and methanol as mobile phase. Various forced degradation studies were conducted to establish an impurity profile for vildagliptin in the tablet formula. Three degradation products were produced upon exposing vildagliptin to different degradation conditions (acidic, basic, oxidative, photolytic, aqueous and thermal); their structures were characterized using LC-MS and NMR (^{1}H NMR, ^{13}C NMR and DEPT) techniques. Some excipient components, examined in this study, had major effect towards producing any extra new degradation products.

Keywords: Vilaglibtin, tablet form, excipients, forced, degradation, impurity profile, 2D-NMR.

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