Stability Indicating High Performance Liquid Chromatographic Determination of Sitagliptin in Bulk Drug and Formulations.

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Abstract
The purpose of this study was to develop a new stability indicating method for the analysis of sitagliptin in formulation and raw material. In the present study a rapid, simple, economical reverse phase HPLC procedure has been developed for the determination of sitagliptin. The sitagliptin was separated isocratically on Hypersil-Gold C18 column (Length- 250 mm, Diameter- 4.6 mm, Particle size- 5 µm) with a mobile phase consisting of 25% acetonitrile, 75% water (containing 0.25 mL/L triethylamine, final pH was adjusted to 2.75±0.10), operated at 25±1 °C with a retention time less than 8 min. The total run time of the stressed study was 20 mins. The eluted drug was identified and monitored on a Photo Diode-Array detector (PDA) at λ=215 nm. The linearity of the method was excellent (r² ≥ 0.9998) over the concentrations range of 2.5–100 µg/ml; the LOD and LOQ were 0.0627 µg/ml and 0.1896 µg/ml respectively. The statistical evaluation of the method was examined by performing intraday and interday precision analysis. The overall precision (% CV, RSD) was less than 2.0 %. Mean recovery of sitagliptin was more than 99.0 %, no interference was found from the other ingredient or component present in the preparation. The result of stability studies indicates that the drug was stable when exposed to direct sunlight, UV light or chemical stress (exposure to 1N HCl or 35% H2O2). The drug gives 2 degraded products on exposure to alkaline condition (NaOH, 1N). The percent of degraded products was 12.2%.

In conclusion the method presented here is sensitive, rapid, accurate, precise, economic, robust, rugged and selective for the routine analysis of the drug in formulation and raw material in presence of degraded products.

Detailed view of the monograph

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