A validated stability indicating HPLC method for determination of sitagliptin

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Abstract

A comparative and stability-indicating reversed phase high performance liquid chromatographic study have been developed and validated for sitagliptin phosphate. The liquid chromatographic determination was achieved isocratically on Poroshell 120 EC-C18 (100 Ĭ 4.6 mm, i.d.; particle size, 2.7 Õm), Pursuit 5PFP (150 Ĭ 4.6 mm, i.d.; particle size, 5 Õm) and Chromolith performance RP-18e (100 Ĭ 4.6 mm, i.d.; macropore diameter, 2 Õm) columns using a mobile phase consisting of methanol:water:triethylamine:acetic acid (60:40:0.1:0.1; v:v:v:v), at a flow rate 0.5 mL/min and UV detection at 268 nm. The method was linear over the concentration range of 100-1000 Õg/mL (r = 0.9998) with a limit of detection and quantitation of 10 and 30 Õg/mL, respectively. All the validation parameters and stability indicating study were studied on Poroshell 120 EC-C18 column, which achieved the best separation. The proposed method has been found to have the required accuracy, selectivity, sensitivity, and precision to assay sitagliptin phosphate in bulk form and in a pharmaceutical dosage form. Degradation products resulting from the stress studies did not interfere with the detection of sitagliptin phosphate that indicates that the assay are stability-indicating assay.

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