

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 342GE/E3: "322" "608" o o."k0f0="rctvkeng"uk|g."409"Û o+."Rwtuwkv"7RHR"*372" "608" o o."k0f0="rctvkeng"uk|g."7"Û o+"cpf"Ej tq o qnkvj " rgthqt o cpeg"TR/3:g"*322" "608" o o."k0f0="o cetqrqtg"fk o gvg t."4"Û o+"eqnw o pu"wukpi "c" o qdkng"rj cug"eqpukvki "qh" 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 tci g"qh"322/3222"Û il o N"*t"?"20; ; ; :+" ykvj "c"nk o kv"qh"fgvkvqp"cpf"swcpvkvkqp"qh" 32"cpf"52"Û il o N."tgur gevkggn{0"Cm"vj g"xcnk fcvkqp"rctc o gvgtu"cpf"uvcdknkv{ "kpfkecvki" 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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