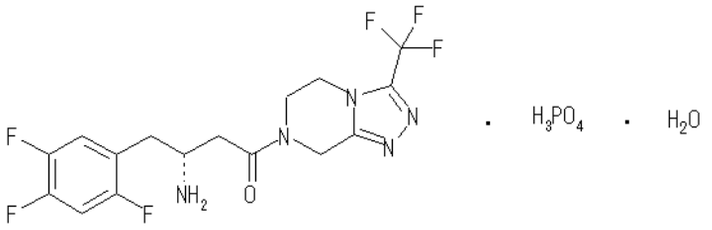
U.S. Pharmacopeia method

DAICEL CORPORATION

Sitagliptin Phosphate :Enantiomeric Purity

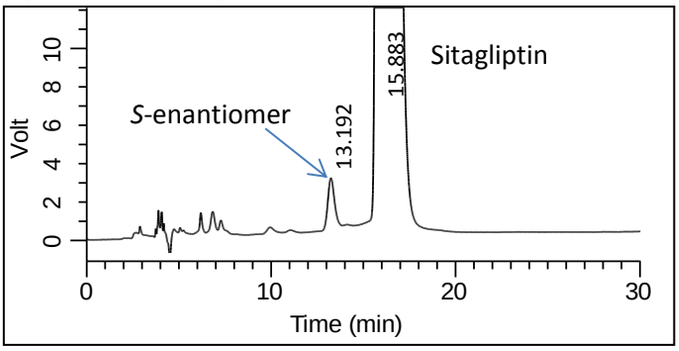


Column	: CHIRALPAK® AD-H 0.46cmΦ × 25cmL (L51)
Mobile phase	: Dehydrated alcohol / n-Heptane / Diethylamine / Water = 600 / 400 / 1 / 1 (v / v / v / v)
Flow rate	: 0.8mL/min.
Column temperature	: 35℃
Injection volume	: 10μL
UV detection	: 268nm

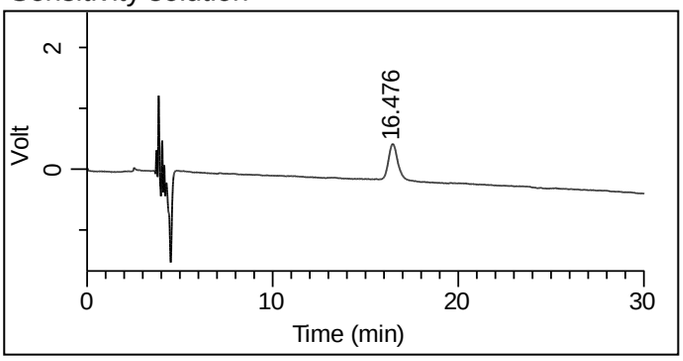
System suitability
System suitability solution:
8 mg/mL of USP Sitagliptin System suitability Mixture RS in *Diluent.*
Sensitivity solution:
8 μg/mL of Sitagliptin Phosphate in *Diluent* from the *Sample solution*.

Relative retention time: Sitagliptin which is the *R*-enantiomer, and the *S*-enantiomer are 1.0 and 0.9, respectively.

System suitability solution



Sensitivity solution



	Requirement	Result
Resolution	≧1.5	3.0
Signal-to-noise ratio	≧10	29.7

For details of monograph, please check pharmacopeia.