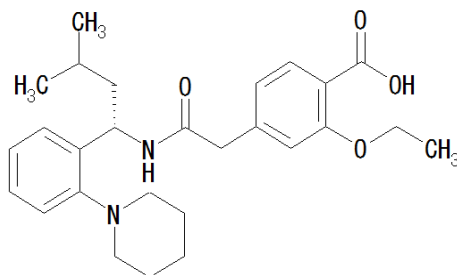


Repaglinide :Enantiomeric Purity



Column : CHIRALPAK® AGP 0.40cmΦ × 10cmL (L41)
 Solution A : Buffer ※
 Solution B : Acetonitrile
 Mobile phase : See below table
 Flow rate : 1.0mL/min.
 Injection volume : 10μL
 UV detection : 240nm

※ Buffer : Dissolve 1 g of monobasic potassium phosphate in 1 L of water. If needed, adjust with 2 N Sodium hydroxide or with dilute phosphoric acid to a pH of 4.7

(Table)

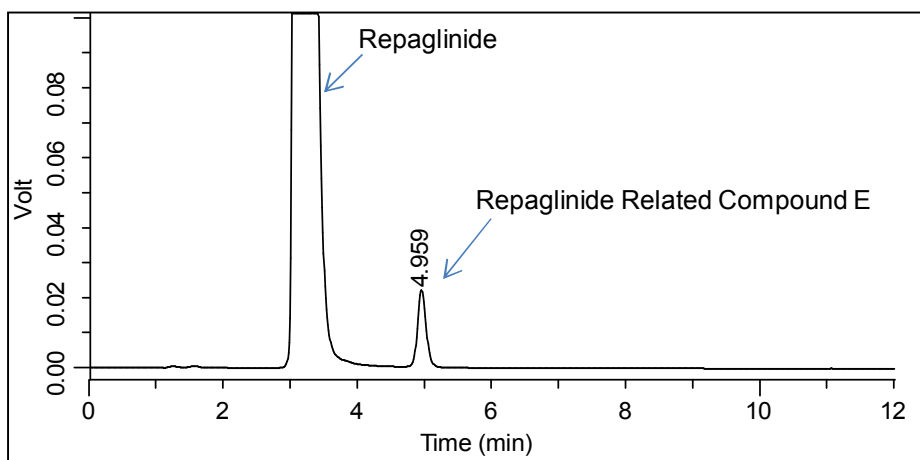
Time (min)	Solution A (%)	Solution B (%)
0	80	20
4	60	40
6	60	40

System suitability

System suitability solution: 1.0 mg/mL of USP Repaglinide RS and 0.02 mg/mL of USP Repaglinide Related Compound E RS in methanol.

Standard solution: 2.0 μg/mL of USP Repaglinide Related Compound E RS in methanol.

Relative retention time: Repaglinide and Repaglinide Related Compound E are 1.0 and 1.5, respectively.



	Requirement	Result
Resolution (<i>System suitability solution</i>)	≥ 1.5	5.5
Relative standard deviation (<i>Standard solution</i>)	≤ 5.0%	0.25%