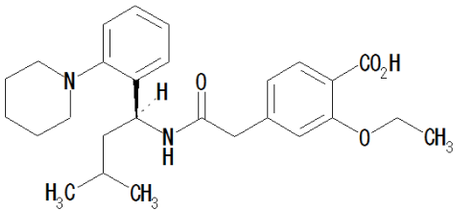
European Pharmacopoeia method

DAICEL CORPORATION

Repaglinide :Enantiomeric purity



Column	: CHIRALPAK® AGP 0.40cmΦ × 10cmL
Mobile phase A	: 1.0 g/L solution of *potassium dihydrogen phosphate R* adjusted to pH 4.7 with *dilute sodium hydroxide solution R*
Mobile phase B	: Acetonitrile *R*
Mobile phase	: See below Table
Flow rate	: 1.0mL/min.
Injection volume	: 10 μL
UV detection	: 240nm

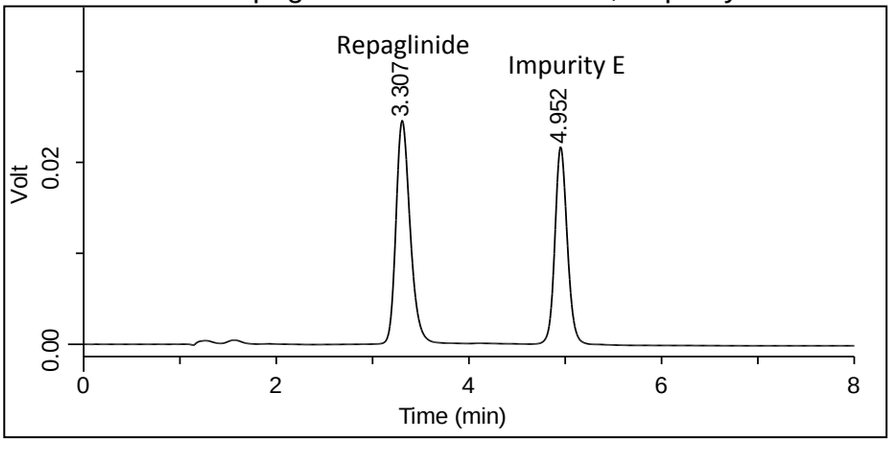
(Table)

Time (min)	Mobile phase A (per cent *V/V*)	Mobile phase B (per cent *V/V*)
0 - 4	80 → 60	20 → 40
4 - 6	60	40

Equilibration after installation of the column for use: Using *water R* , slowly increase the flow rate from 0.2 mL/min. to 0.5 mL/min. Maintain the flow rate at 0.5 mL/min. for 5 min.
The column must be washed for 1 h at a flow rate of 1 mL/min. with *water R* and for 1 h with the mobile phase at the initial composition prior to the 1st analysis.

System suitability
Reference solution (c):
Mix 1.0 mL of test solution and 10 mL of reference solution (a) and dilute to 50.0 mL with *methanol R*.

Retention time: Repaglinide = about 3.3 min. ; impurity E = about 5.0 min.



	Requirement	Result
Resolution	Minimum 1.5 between the peaks due to Repaglinide and impurity E (reference solution (c))	6.3

For details of monograph, please check pharmacopoeia.