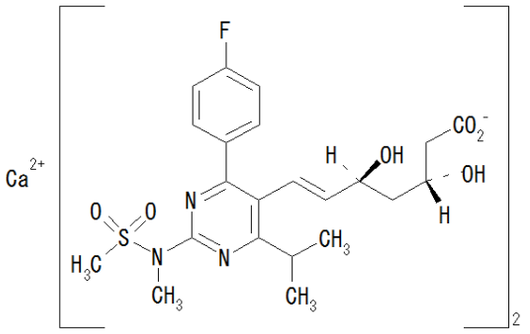
European Pharmacopoeia method

DAICEL CORPORATION

Rosuvastatin calcium :Enantiomeric purity



Column	: CHIRALCEL® OJ-RH 0.46cmΦ × 15cmL
Mobile phase	: Acetonitrile *R* / 0.1% V/V solution of Trifluoroacetic acid *R* = 25 / 75 (V/V)
Flow rate	: 0.5mL/min.
Injection volume	: 10μL
Column temperature	: 35℃
UV detection	: 242nm

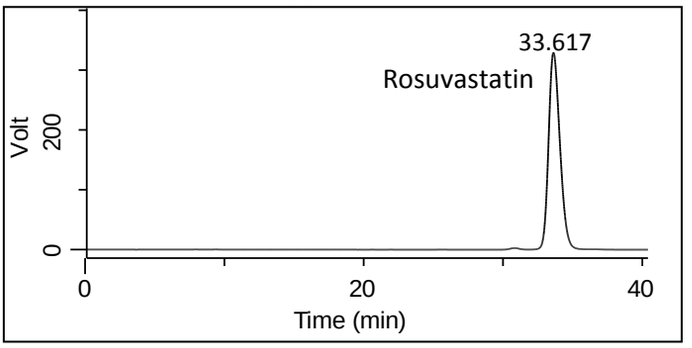
System suitability

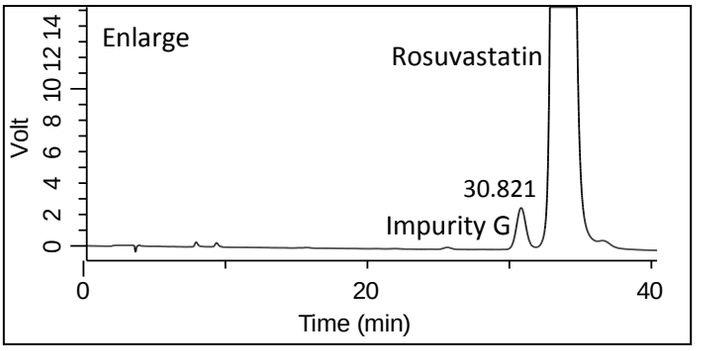
Reference solution (b):

Dissolve the contents of a vial of *Rosuvastatin impurity G CRS* in 1.0 mL of the test solution.

Relative retention with reference to Rosuvastatin (retention time = about 29 min.):
impurity G = about 0.9

Reference solution (b)





	Requirement	Result
Resolution	Minimum 1.5 between the peaks due to impurity G and Rosuvastatin (reference solution (b))	2.08

For details of monograph, please check pharmacopoeia