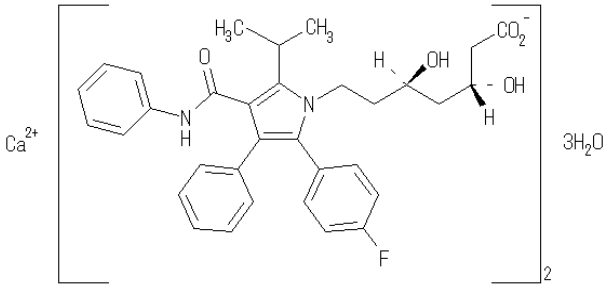
European Pharmacopoeia method

DAICEL CORPORATION

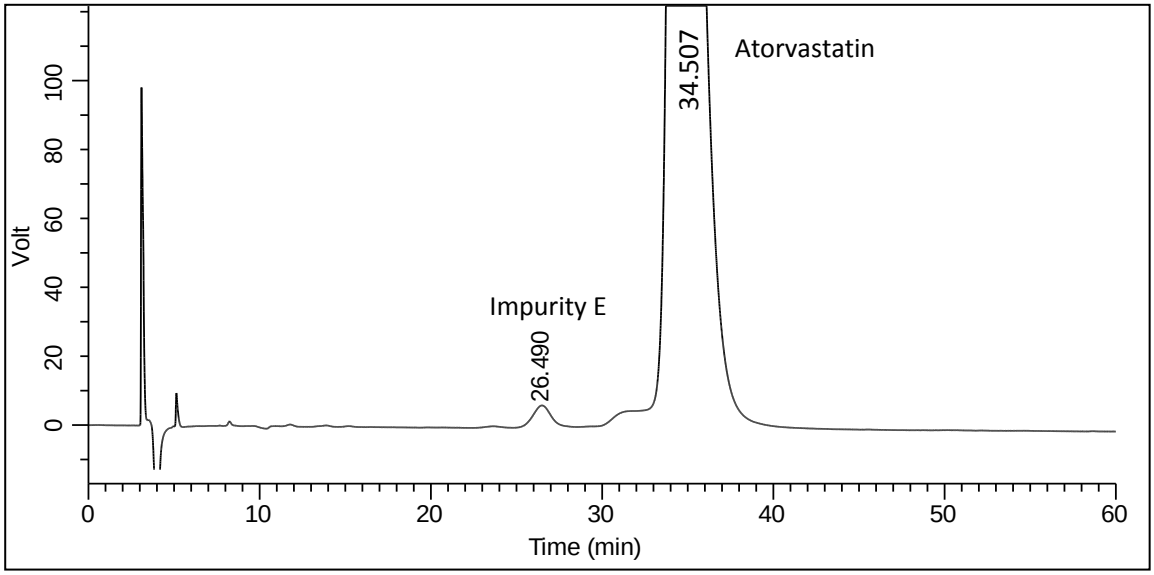
Atorvastatin calcium trihydrate :Enantiomeric purity



Column	: CHIRALPAK® AD 0.46cmΦ × 25cmL
Mobile phase	: Trifluoroacetic acid *R* / Anhydrous ethanol *R* / Hexane *R* = 0.1 / 6 / 94 (v / v / v)
Flow rate	: 1.0mL/min.
Injection volume	: 20μL
UV detection	: 244nm

System suitability
Reference solution (a):
Dissolve 2 mg of *Atorvastatin impurity E CRS* in *methanol R* and dilute to 20.0 mL with the same solvent (solution A). Dissolve 10 mg of the substance to be examined in 1.25 mL of *methanol R*, add 0.75 mL of solution A and 2 mL of *anhydrous ethanol R* and dilute to 10.0 mL with hexane R.

Relative retention with reference to Atorvastatin (retention time = about 44 min):
impurity E = about 0.8



	Requirement	Result
Resolution	Minimum 2.0 between the peaks due to impurity E and Atorvastatin (reference solution (a))	3.4

For details of monograph, please check pharmacopoeia