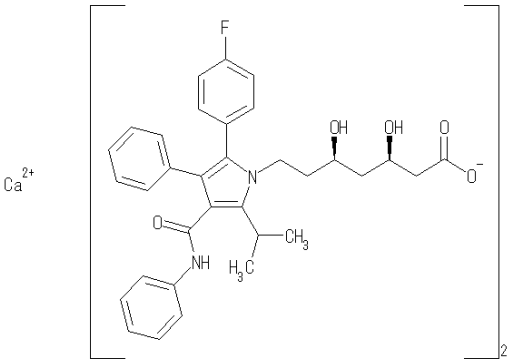
U.S. Pharmacopeia method

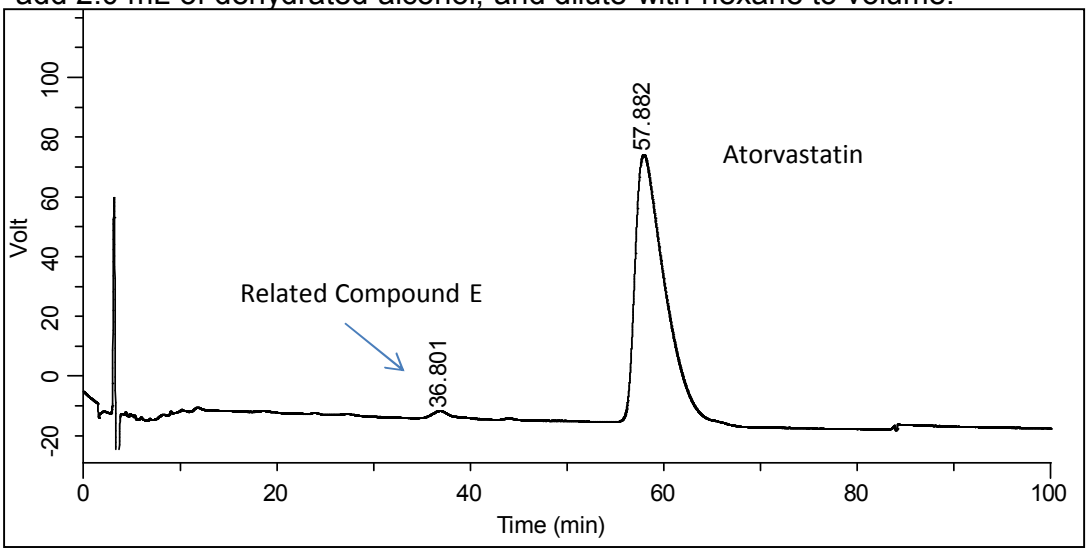
DAICEL CORPORATION

Atorvastatin Calcium :Enantiomeric Purity



Column	: CHIRALPAK® AD-H 0.46cmΦ × 25cmL (L51)
Mobile phase	: Hexane / dehydrated alcohol / trifluoroacetic acid = 940 / 60 / 1 (v / v / v)
Flow rate	: 1.0mL/min.
Injection volume	: 20μL
UV detection	: 244nm

System suitability
System suitability stock solution:
5 mg/mL of USP Atorvastatin Calcium RS and 37.5 μg/mL of USP Atorvastatin Related Compound E RS in methanol.
System suitability solution:
Transfer 2.0 mL of the *System suitability stock solution* to a 10-mL volumetric flask, add 2.0 mL of dehydrated alcohol, and dilute with hexane to volume.



	Requirement	Result
Resolution	≧2.0	5.0