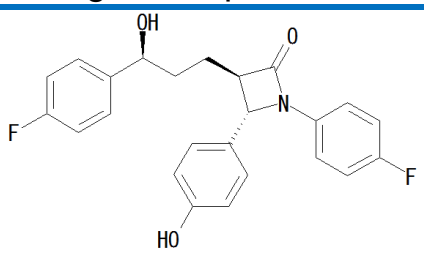
U.S. Pharmacopeia method

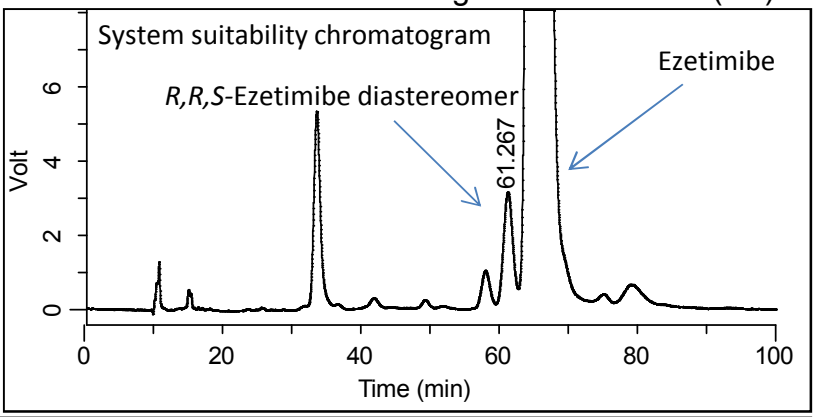
DAICEL CORPORATION

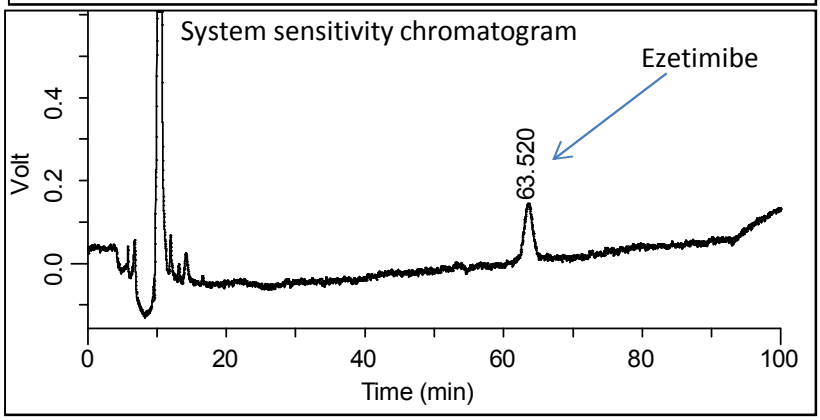
Ezetimibe :Organic impurities, Procedure 2



Column	: CHIRALCEL® OD-RH 0.46cmΦ × 15cmL (Two columns in series)
Mobile phase	: Acetonitrile / Water = 450 / 550 (v / v)
Flow rate	: 0.35mL/min.
Injection volume	: 10μL
Column temperature	: 5℃
UV detection	: 248nm

System suitability
Sample: 0.4 mg/mL of USP Ezetimibe System Suitability Mixture RS in *Diluent*.
System sensitivity
Sample: 0.2 μg/mL of USP Ezetimibe RS in *Diluent*.
Diluent : Acetnitrile with 0.1% glacial acetic acid (v/v)





	Requirement	Result
Resolution between ezetimibe and R,R,S-ezetimibe diastereomer (*System suitability solution*)	≧1.5	1.6
Tailing factor for the ezetimibe peak (*System suitability solution*)	≦1.5	1.2
Relative standard deviation (*Sensitivity solution*)	≦10 %	5.7%