European Pharmacopoeia method



Lacosamide: Enantiomeric purity

Column : CHIRALPAK[®] AD-H 0.46cmΦ × 25cmL

Mobile phase : Water R / 2-propanol R / Heptane R = 3 / 100 / 900 (v / v / v)

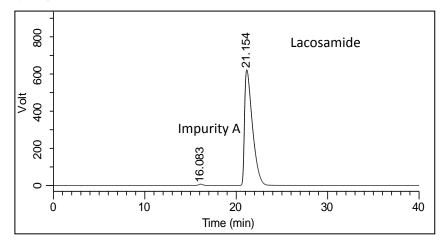
Flow rate : 1.0mL/min.
Injection volume : 20µL
UV detection : 215nm

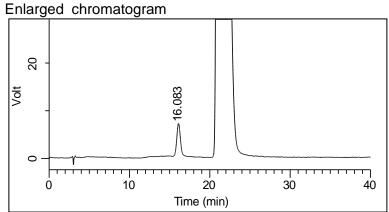
System suitability

Reference solution (b):

Dissolve 20.0 mg of the substance to be examined in the mobile phase, add 1.0 mL of reference solution (a) and dilute to 20.0 mL with the mobile phase.

Relative retention with reference to Lacosamide (retention time = about 25 min): impurity A = about 0.8





	Requirement	Result
Resolution	Minimum 4.0 between the peaks due to impurity A and Lacosamide (reference solution (b))	4.3