European Pharmacopoeia method



Solifenacin succinate :Isomeric purity

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

Mobile phase : Diethylamine / Anhydrous ethanol / Heptane = 0.1 / 200 / 800 (v / v / v)

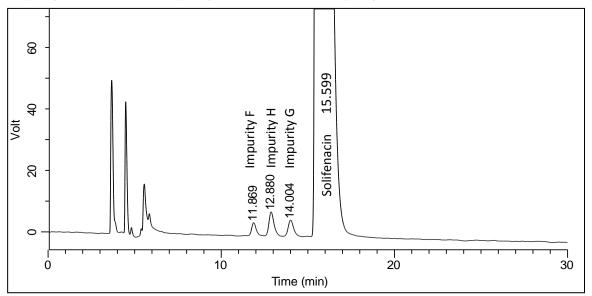
Flow rate : 0.8mL/min.
Injection volume : 10µL
Column temperature : 35°C
UV detection : 220nm

System suitability

Reference solution (a):

Dissolve the contents of a vial of *Solifenacin for system suitability CRS* (containing impurities F, G and H) in 1.0 mL of the mobile phase.

Relative retention with reference to Solifenacin (retention time = about 17 min): impurity F = about 0.7; impurity H = about 0.76; impurity G = about 0.84.



	Requirement	Result
Resolution	Minimum 1.5 between the peaks due to impurities F and H	2.1
Peak-to-valley ratio	Minimum 10, where H_p = height above the baseline of the peak due to impurity G and H_v = height above the baseline of the lowest point of the curve separating this peak from the peak due to impurity-H.	108