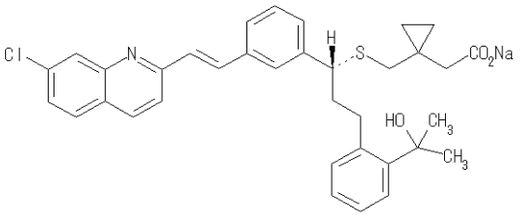
European Pharmacopoeia method

DAICEL CORPORATION

Montelukast Sodium :Enantiomeric purity



Column	: CHIRALPAK® AGP 0.40cmΦ × 15cmL
Mobile phase A	: 2.3 g/L solution of ammonium acetate R adjusted to pH 5.7 with glacial acetic acid R.
Mobile phase B	: Acetonitrile R / Methanol R = 40 / 60 (v / v)
Mobile phase	: See below Table
Flow rate	: 0.9 mL/min.
Column temperature	: 30℃
Injection volume	: 10 μL
UV detection	: 280nm

(Table)

Time (min)	Mobile phase A (per cent *V/V*)	Mobile phase B (per cent *V/V*)
0 - 30	70 → 60	30 → 40
30 - 35	60	40

System suitability

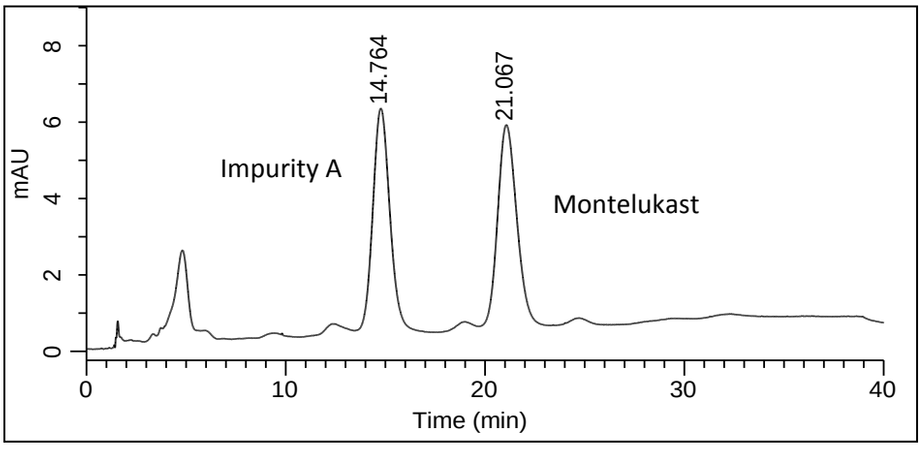
Reference solution (a):

Dilute 1.0 mL of the test solution to 100.0 mL with the solvent mixture. Dilute 1.0 mL of this solution to 10.0 mL with the solvent mixture.

Reference solution (b):

Dissolve 5 mg of Montelukast racemate CRS in the solvent mixture and dilute to 50.0 mL with the solvent mixture.

Relative retention with reference to Montelukast (retention time = about 25 min): impurity A = about 0.7.



	Requirement	Result
Resolution	Minimum 2.9 between the peaks due to impurity A and Montelukast (reference solution (b))	3.8
Signal-to-noise ratio	Minimum 10 for the principal peak in the chromatogram obtained with reference solution (a).	19.8

For details of monograph, please check pharmacopoeia.