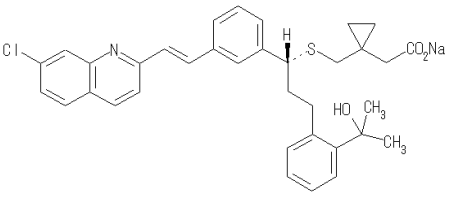
Japanese Pharmacopoeia method

DAICEL CORPORATION

Montelukast Sodium :Optical isomer



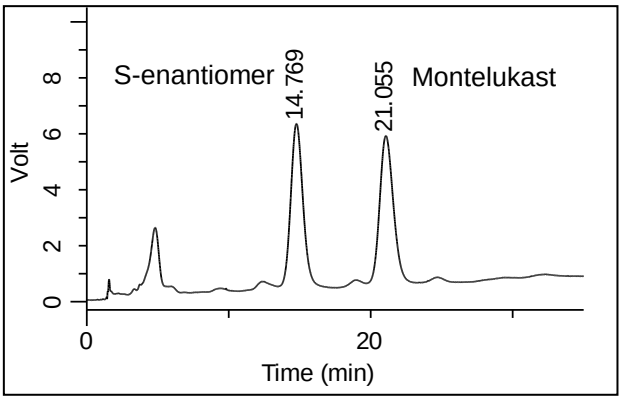
Column	: CHIRALPAK® AGP 0.40cmΦ × 15cmL
Mobile phase A	: Dissolve 2.3 g of ammonium acetate in 1000 mL of water, and adjust to pH 5.7 with acetic acid (100).
Mobile phase B	: Methanol / Acetonitrile = 3 / 2 (v / v)
Mobile phase	: See below table
Flow rate	: 0.9mL/min.
Temperature	: 30℃
Injection volume	: 10μL
UV detection	: 280nm

(Table)

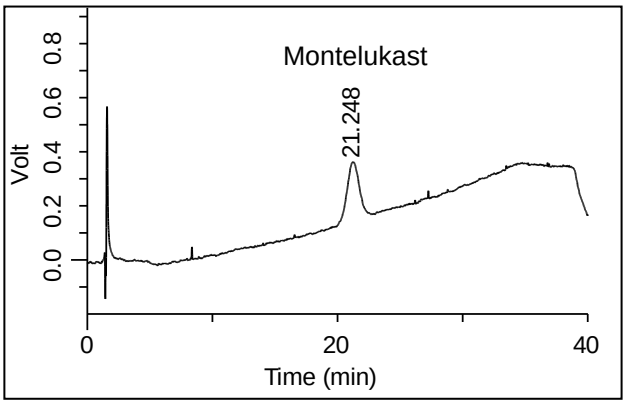
Time after injection of sample (min)	Mobile Phase A (vol%)	Mobile PhaseB (vol%)
0 - 30	70 → 60	30 → 40
30-35	60	40

System suitability solution
Test for required detectability:
Pipet 1 mL of the sample solution, add the mixture of water and acetonitrile (1:1) to make exactly 100 mL. Pipet 1 mL of this solution, add the mixture of water and acetonitrile (1:1) to make exactly 10 mL.
Test for system performance:
Montelukast Racemate RS for System Suitabillity in the mixture of water and acetonitrile (1:1) (1 in10,000)

System performance



Detectability



	Requirement	Result
Resolution	≧2.9	3.8
Signal-to-noise ratio	≧10	19.8

For details of monograph, please check pharmacopeia.