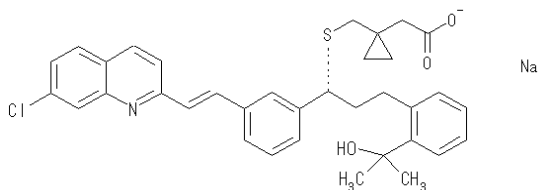


Montelukast Sodium : Enantiomeric Purity



Column : CHIRALPAK® AGP 0.40cmΦ × 15cmL (L41)
 Solution A : 2.3 g/L of ammonium acetate in water. Adjust with glacial acetic acid to a pH of 5.7.
 Solution B : Methanol / Acetonitrile = 60 / 40 (v / v)
 Mobile phase : See below table
 Flow rate : 0.9mL/min.
 Temperature : 30°C
 Injection volume : 10μL
 UV detection : 280nm
 (Table)

Time (min)	Solution A (%)	Solution B (%)
0	70	30
30	60	40
35	60	40

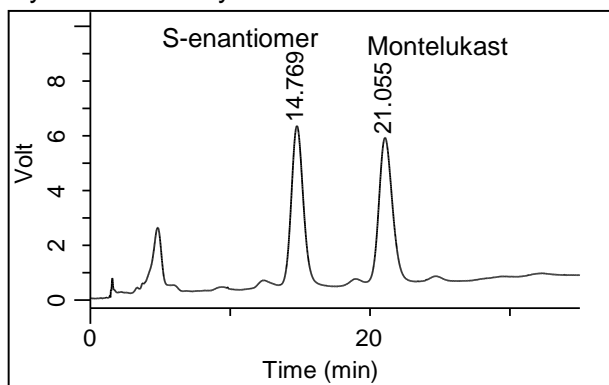
System suitability

System suitability solution: 0.1 mg/mL of USP Montelukast Racemate RS in *Diluent*.

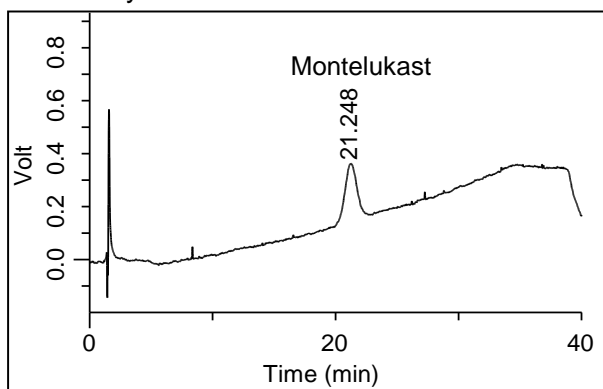
Sensitivity solution: 1 μg/mL of Montelukast Sodium in *Diluent* from the *sample solution*.

Relative retention times: 1.0 for Montelukast, which is the *R*-enantiomer, and 0.7 for the *S*-enantiomer.

System suitability solution



Sensitivity solution



	Requirement	Result
Resolution (<i>System suitability solution</i>)	≥ 2.9	3.8
Signal-to-noise ratio (<i>Sensitivity solution</i>)	≥ 10	19.8

For details of monograph, please check pharmacopeia.