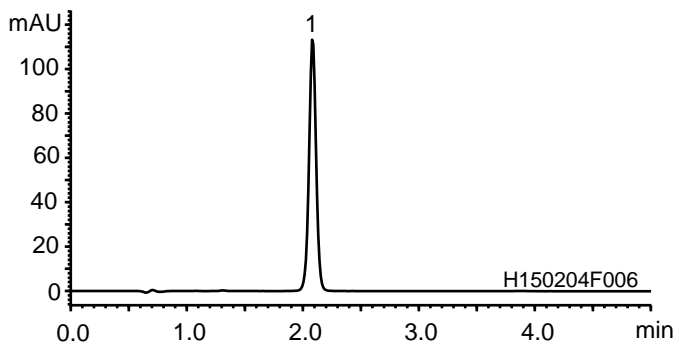


モンテルカストナトリウム錠 (米国薬局方原案記載条件)

Montelukast sodium tablets (The draft for The United States Pharmacopoeia)

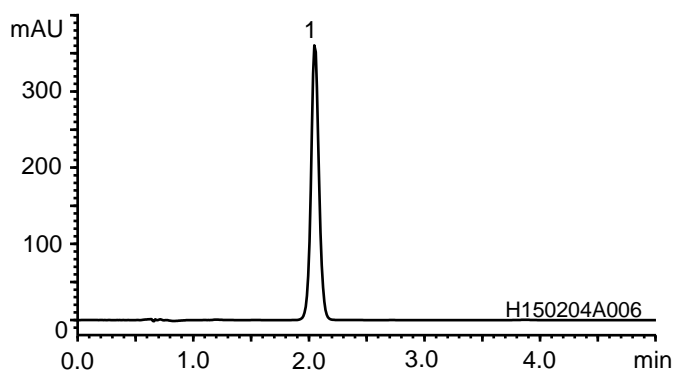
H150501B

(A) Dissolution: Standard solution^{*1}
(5.4 µg/mL Montelukast)



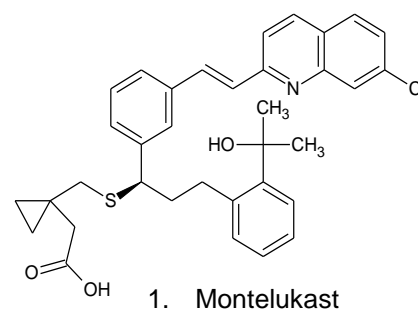
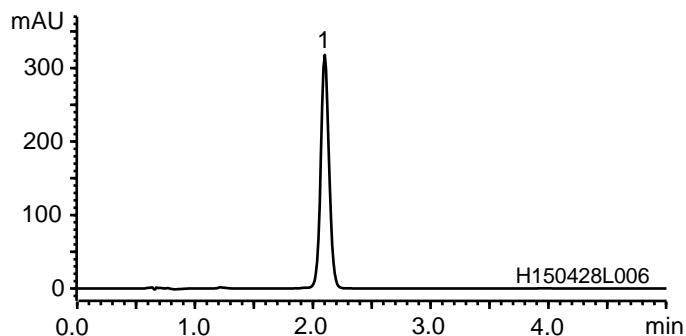
	System suitability requirement	Result
Tailing factor (Montelukast)	≤ 1.5	1.08
Relative standard deviation of peak area (n=5) (Montelukast)	≤ 2.0%	0.05%

(B) Uniformity of dosage units: Standard solution^{*1}
(0.039 mg/mL Montelukast)



	System suitability requirement	Result
Tailing factor (Montelukast)	≤ 1.5	1.15
Relative standard deviation of peak area (n=5) (Montelukast)	≤ 2.0%	0.06%

(C) Uniformity of dosage units: Sample solution^{*2}
(0.04 mg/mL Montelukast)



Column : YMC-Pack Ph (5 µm, 12 nm)
100 X 3.0 mm I.D.
Eluent : acetonitrile/water/TFA (500/500/2)
Flow rate : 0.9 mL/min
Temperature : 50°C
Detection : UV at 389 nm
Injection : A) 20 µL, B), C) 10 µL

(The draft for The United States Pharmacopoeia 40th; Dissolution, Uniformity of dosage units)

^{*1} All Standard solutions were prepared from Montelukast sodium salt hydrate supplied as a reagent for laboratory use.

^{*2} Sample solution was prepared from Montelukast sodium tablets.