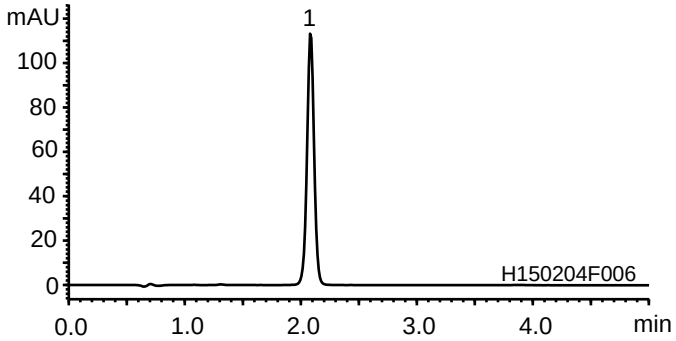
HPLC DATA SHEET

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)

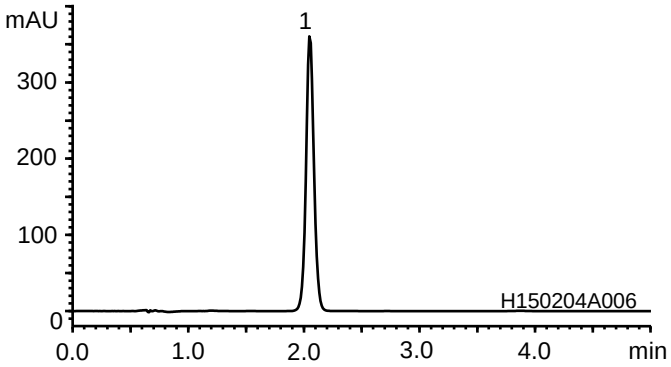
H150501B

(A) Dissolution: Standard solution[*1]
(5.4 µg/mL Montelukast)



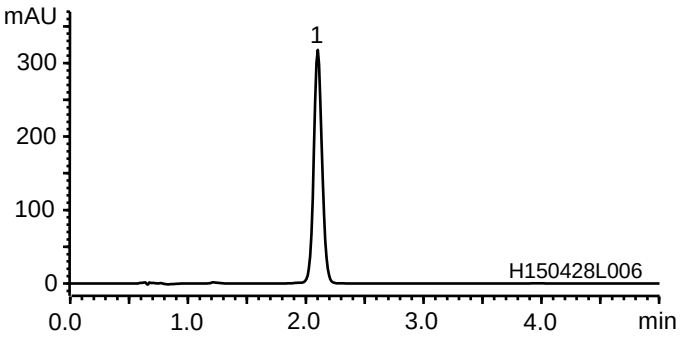
	System suitability requirement	Result
Tailing factor (Montelukast)	≦1.5	1.08
Relative standard devition of peak area (n=5) (Montelukast)	≦2.0%	0.05%

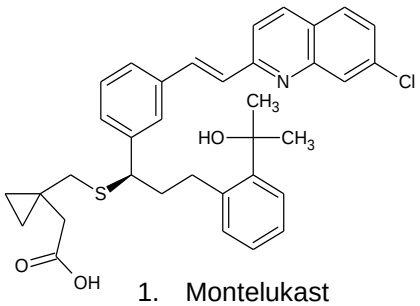
(B) Uniformity of dosage units: Standard solution[*1]
(0.039 mg/mL Montelukast)



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

(C) Uniformity of dosage units: Sample solution[*2]
(0.04 mg/mL Montelukast)





1. Montelukast

Column	: YMC-Pack Ph (5 µm, 12 nm) 100 X 3.0 mmI.D.
Eluent	: acetonitrile/water/TFA (500/500/2)
Flow rate	: 0.9 mL/min
Temperature	: 50℃
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 ware prepared from Montelukast sodium salt hydrate supplied as a reagent for laboratory use.

[*2] Sample solution was prepared from Montelukast sodium tablets.