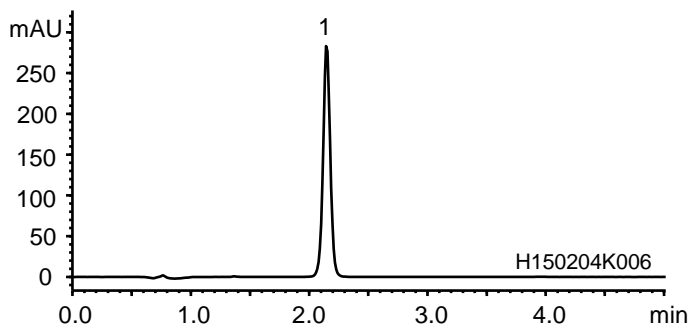


モンテルカストナトリウム錠 (日本薬局方原案記載条件)
 Montelukast sodium tablets (The draft for The Japanese Pharmacopoeia)

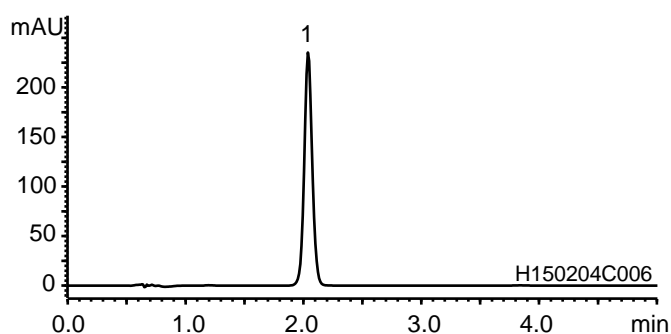
H150501A

(A) Dissolution: Standard solution¹
 (5.5 µg/mL Montelukast)



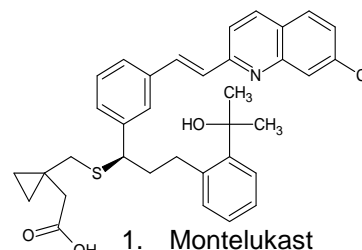
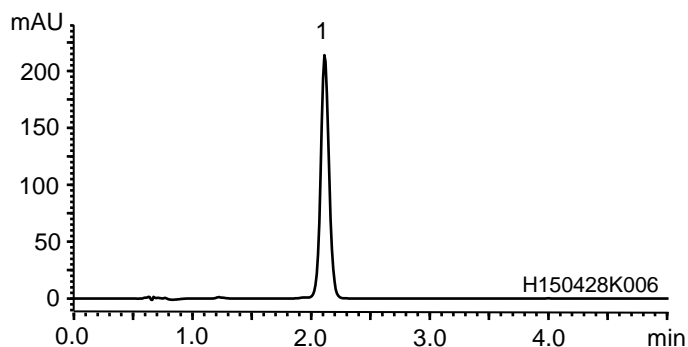
	System suitability requirement	Result
Theoretical plate number (Montelukast)	≥2000	6100
Tailing factor (Montelukast)	≤1.5	1.10
Relative standard deviation of peak area (n=5) (Montelukast)	≤2.0%	0.05%

(B) Uniformity of dosage units: Standard solution¹
 (0.025 mg/mL Montelukast)



	System suitability requirement	Result
Theoretical plate number (Montelukast)	≥2000	4500
Tailing factor (Montelukast)	≤1.5	1.13
Relative standard deviation of peak area (n=5) (Montelukast)	≤1.0%	0.06%

(C) Uniformity of dosage units: Sample solution²
 (0.025 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 (adjust the flow rate so that the retention time of montelukast is about 2 min)
 Temperature : 50°C
 Detection : UV at 389 nm
 Injection : A) 50 µL, B),C) 10 µL

(The draft for The Japanese Pharmacopoeia 17th; 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.