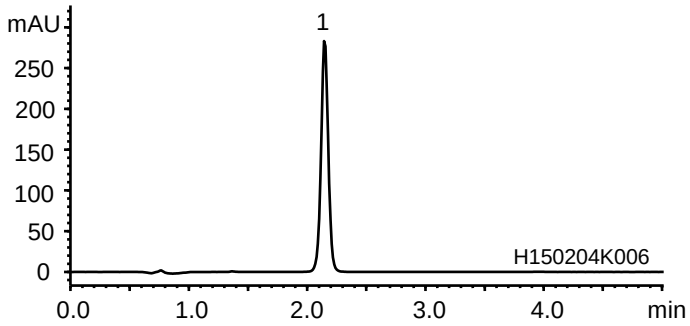
HPLC DATA SHEET

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)

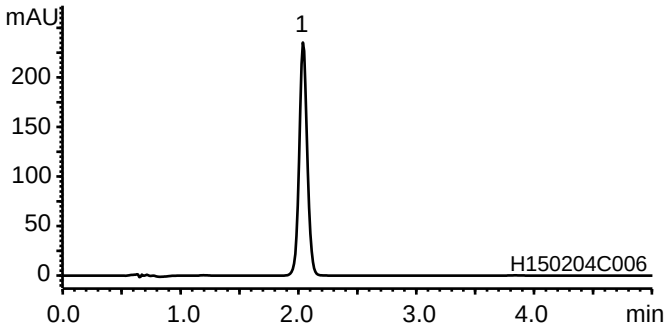
H150501A

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



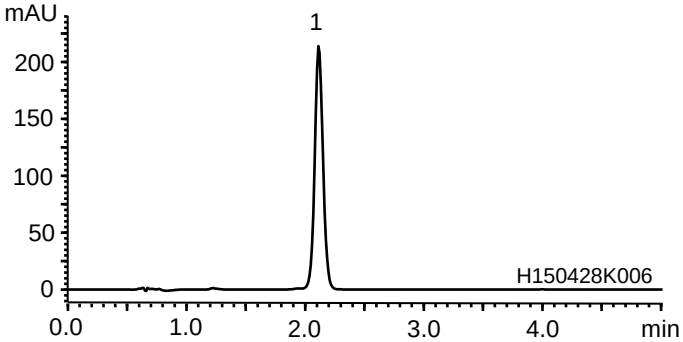
	System suitability requirement	Result
Theoretical plate number (Montelukast)	≧2000	6100
Tailing factor (Montelukast)	≦1.5	1.10
Relative standard devition of peak area (n=5) (Montelukast)	≦2.0%	0.05%

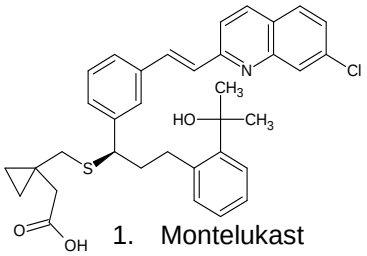
(B) Uniformity of dosage units: Standard solution[*1]
(0.025 mg/mL Montelukast)



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

(C) Uniformity of dosage units: Sample solution[*2]
(0.025 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 *(adjust the flow rate so that the retention time of montelukast is about 2 min)*
Temperature	: 50℃
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 ware prepared from Montelukast sodium salt hydrate supplied as a reagent for laboratory use.

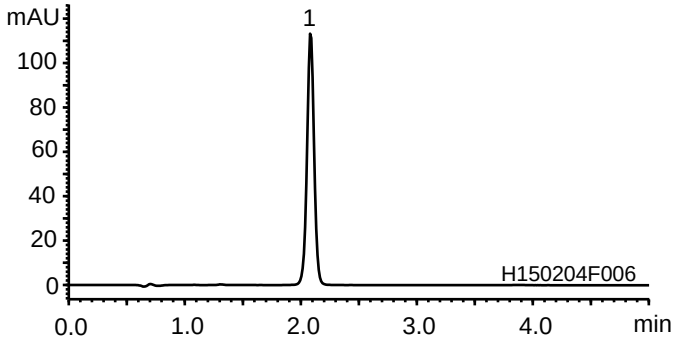
[*2] Sample solution was prepared from Montelukast sodium tablets.

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)

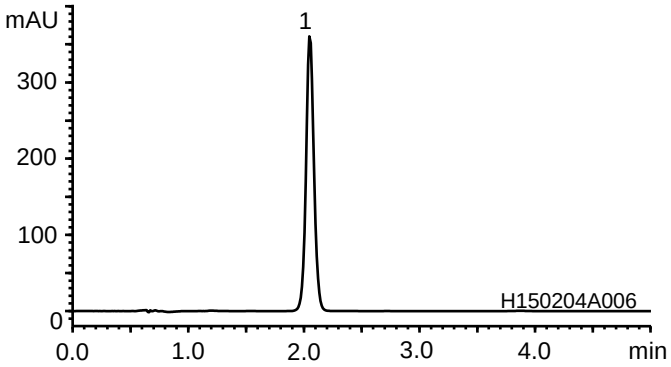
H150501B

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



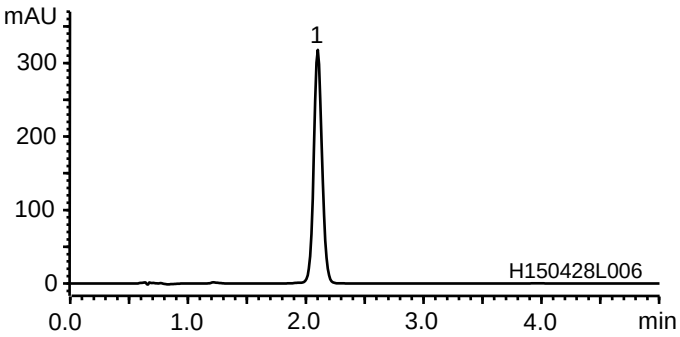
	System suitability requirement	Result
Tailing factor (Montelukast)	≦1.5	1.08
Relative standard devition of peak area (n=5) (Montelukast)	≦2.0%	0.05%

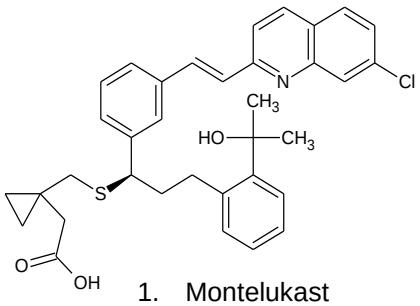
(B) Uniformity of dosage units: Standard solution[*1]
(0.039 mg/mL Montelukast)



	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.

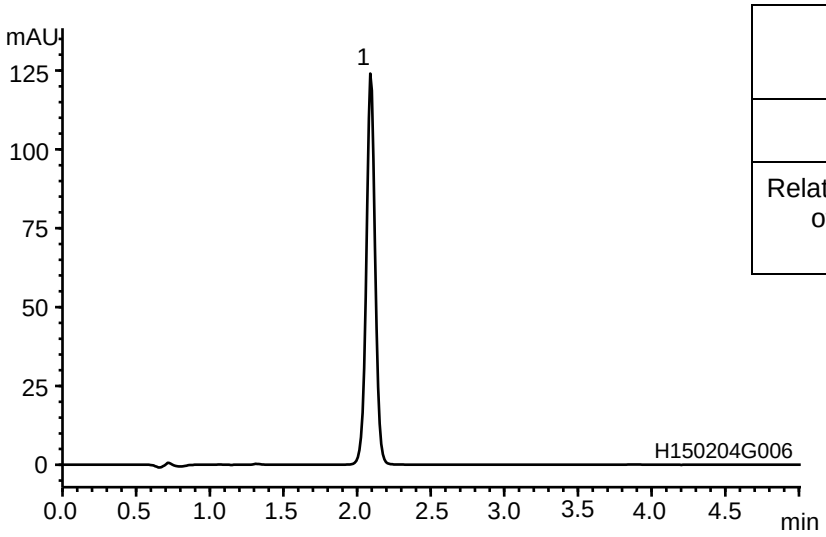
[*2] Sample solution was prepared from Montelukast sodium tablets.

HPLC DATA SHEET

モンテルカストナトリウム顆粒（米国薬局方原案記載条件）
Montelukast sodium oral granules　(The draft for The United States Pharmacopoeia)

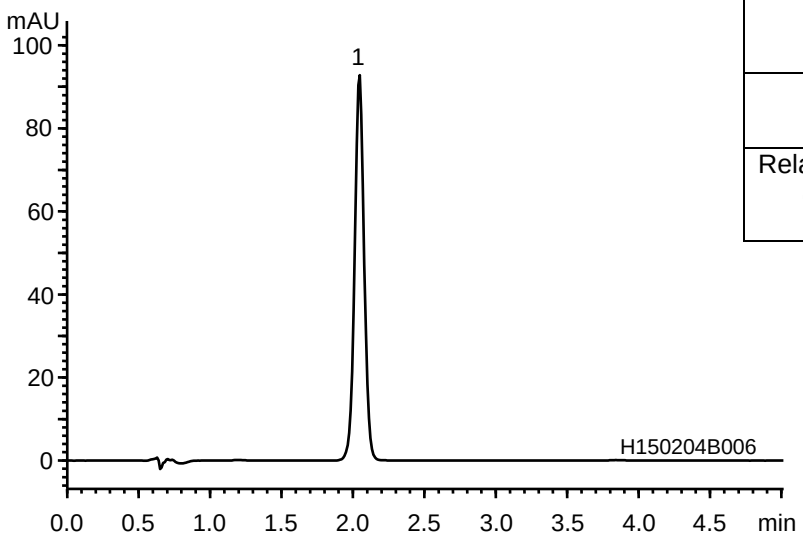
H150501C

(A) Dissolution: Standard solution
(4.4 µg/mL Montelukast)

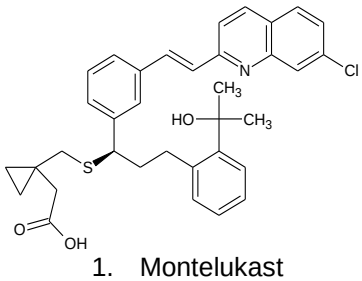


	System suitability requirement	Result
Tailing factor (Montelukast)	≦1.5	1.08
Relative standard devition of peak area (n=5) (Montelukast)	≦2.0%	0.12%

(B) Uniformity of dosage units: Standard solution
(0.020 mg/mL Montelukast)



	System suitability requirement	Result
Tailing factor (Montelukast)	≦1.5	1.09
Relative standard devition of peak area (n=5) (Montelukast)	≦2.0%	0.15%



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) 25 µL, B) 5 µL

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

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