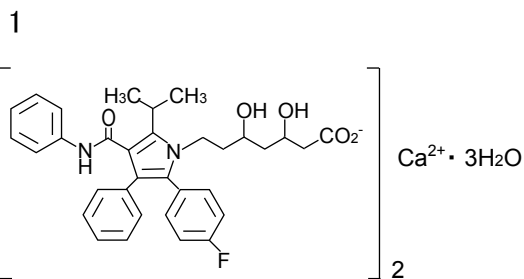
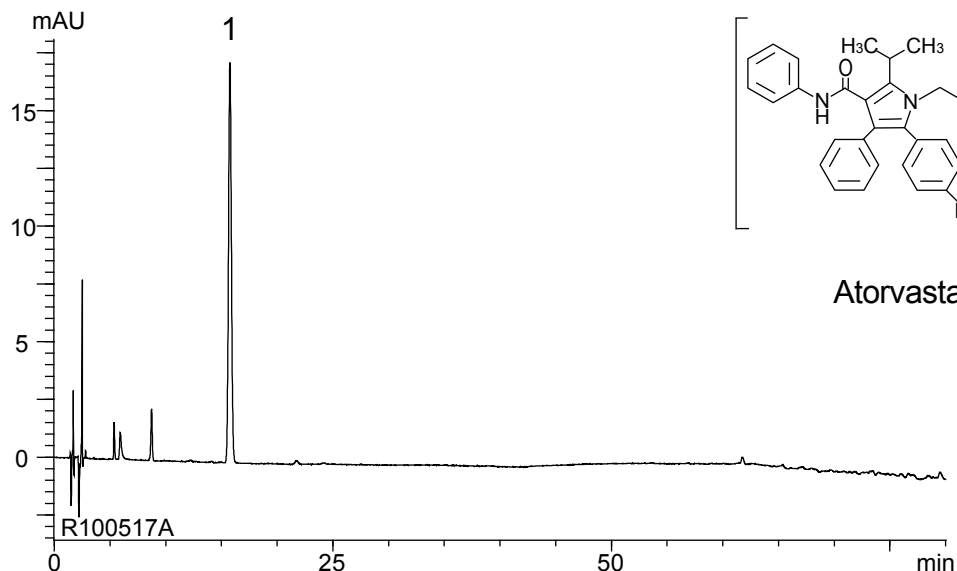


アトルバスタチンカルシウム水和物
Atorvastatin calcium hydrate

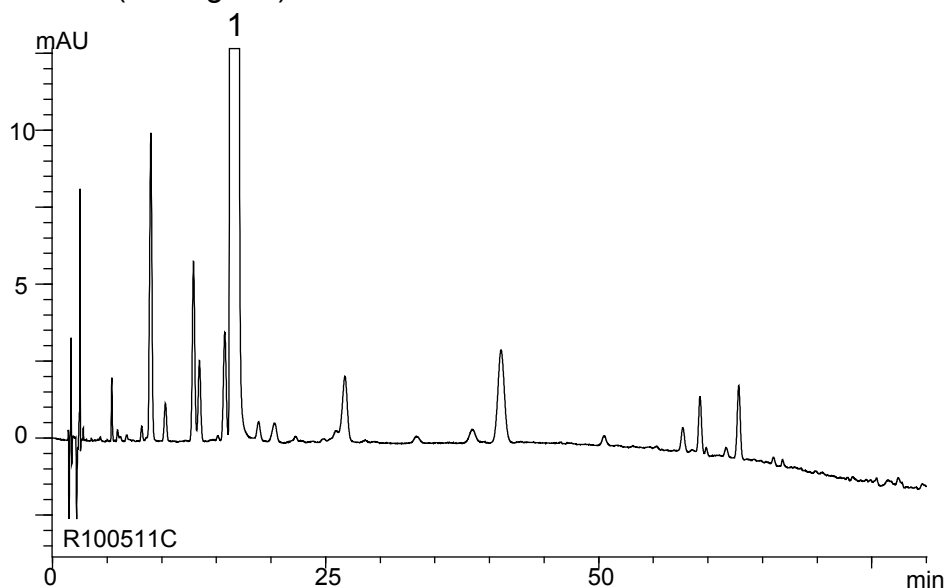
R100421E

標準溶液 (0.01 mg/mL)



Atorvastatin calcium hydrate

試料溶液 (1.0 mg/mL)



Column : YMC-Pack Pro C18 RS (5 μm, 8 nm)
250 X 4.6 mm I.D.

Eluent : A) citric acid buffer*/acetonitrile/THF (40/10/10)
B) acetonitrile/THF (1/1)
7%B (0-40 min), 7-40%B (40-80 min)
*Dissolve 10.5 g citric acid monohydrate in 900 mL water
→ adjust pH 5.0 by 28% ammonia → add water to make 1000 mL

Flow rate : 1.3 mL/min

Temperature : 40°C

Detection : UV at 254 nm

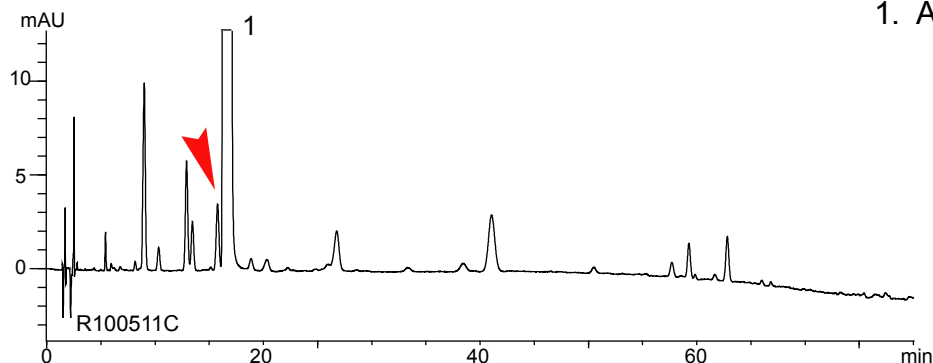
Injection : 20 μL

(日本薬局方収載原案記載条件; 純度試験)

アトルバスタチンカルシウム水和物 (日本薬局方収載原案記載条件; 純度試験)
- 各種C18カラムとの比較 -

R100507A

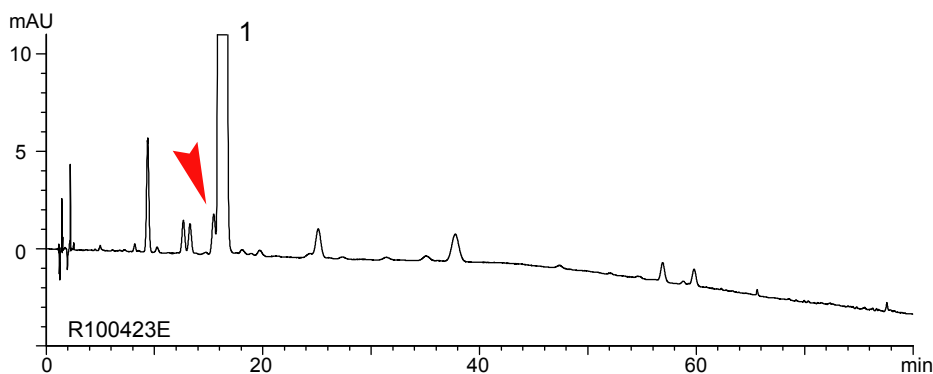
YMC-Pack Pro C18 RS



1. Atorvastatin calcium hydrate

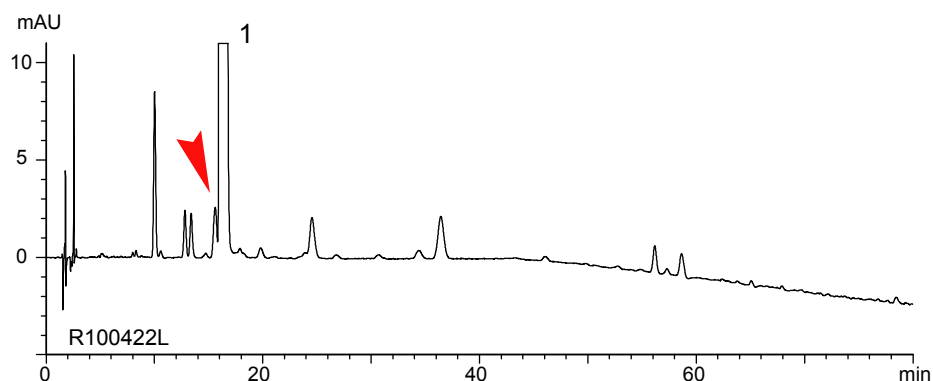
1.3 mL/min
17.2-15.3 MPa

YMC-Triart C18



1.7 mL/min
18.2-15.8 MPa

YMC-Pack ODS-A



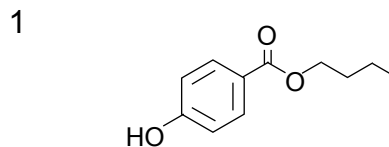
1.4 mL/min
20.5-18.1 MPa

Column : 250 X 4.6 mm I.D. (5 μm)
 Eluent : A) citric acid buffer[※]/acetonitrile/THF (40/10/10)
 B) acetonitrile/THF (1/1)
 7%B (0-40 min), 7-40%B (40-80 min)
[※]Dissolve 10.5 g citric acid monohydrate in 900 mL water
 → adjust pH 5.0 by 28% ammonia → add water to make 1000 mL
 Temperature : 40°C
 Detection : UV at 254 nm
 Injection : 20 μL (1.0 mg/mL)

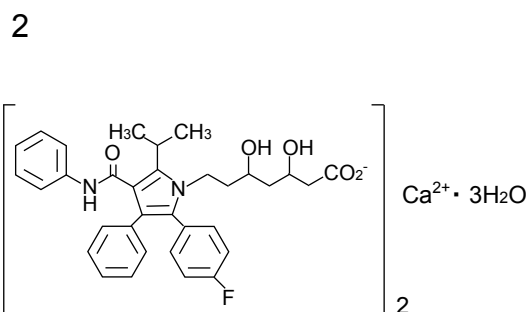
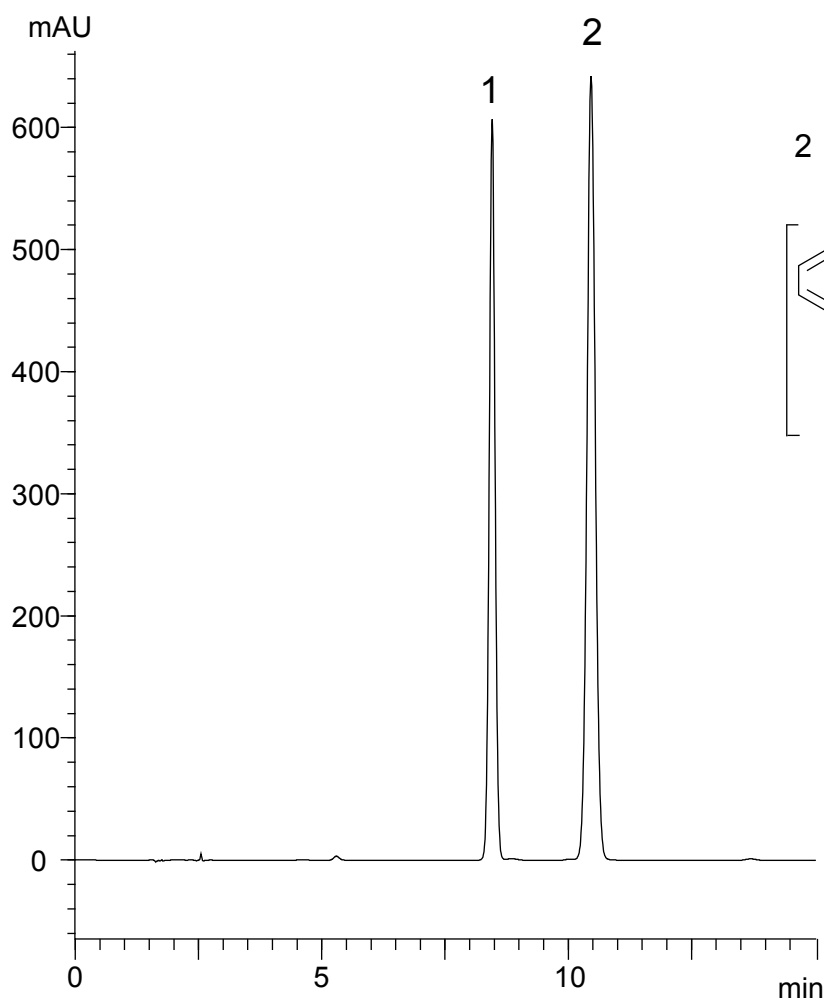
(日本薬局方収載原案記載条件; 純度試験)

アトルバスタチンカルシウム水和物
Atorvastatin calcium hydrate

R100422H



Butyl 4-hydroxybenzoate (I.S.)



Atorvastatin calcium hydrate

Column : YMC-Pack Pro C18 RS (5 μm, 8 nm)
250 X 4.6 mm I.D.

Eluent : citric acid buffer*/acetrontrile/THF (53/27/20)
*Dissolve 10.5 g citric acid monohydrate in 900 mL water
→ adjust pH 4.0 by 28% ammonia → add water to make 1000 mL

Flow rate : 1.2 mL/min

Temperature : 40°C

Detection : UV at 254 nm

Injection : 10 μL (0.13, 0.4 mg/mL)

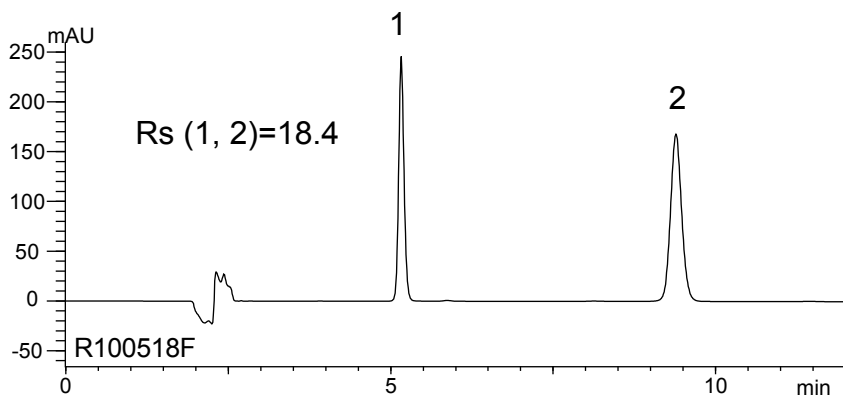
(日本薬局方収載原案記載条件; 定量法)

アトルバスタチンカルシウム錠

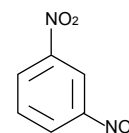
Atorvastatin calcium tablets

R100518P

製剤均一性 (0.04 mg/mL, 0.11 mg/mL, 10 μ L inj.)

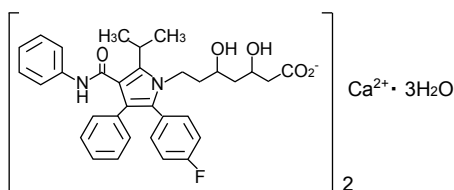


1



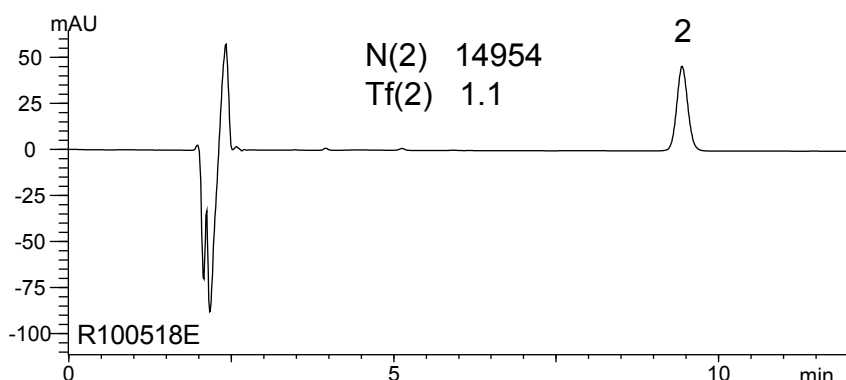
1,3-Dinitrobenzene (I.S.)

2

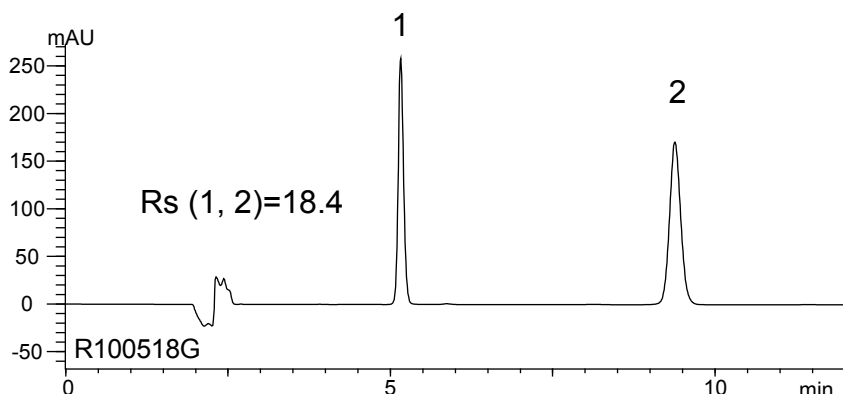


Atorvastatin calcium hydrate

溶出性 (0.006 mg/mL, 50 μ L inj.)



定量法 (0.04 mg/mL, 0.11 mg/mL, 10 μ L inj.)



Column : YMC-Pack ODS-A (5 μ m, 20 nm)
250 X 4.6 mm I.D.
Eluent : citric acid buffer*/acetonitrile/THF (53/27/20)
*Dissolve 10.5 g citric acid monohydrate in 900 mL water
→ adjust pH 4.0 by 28% ammonia → add water to make 1000 mL
Flow rate : 1.3 mL/min
Temperature : 30°C
Detection : UV at 244 nm

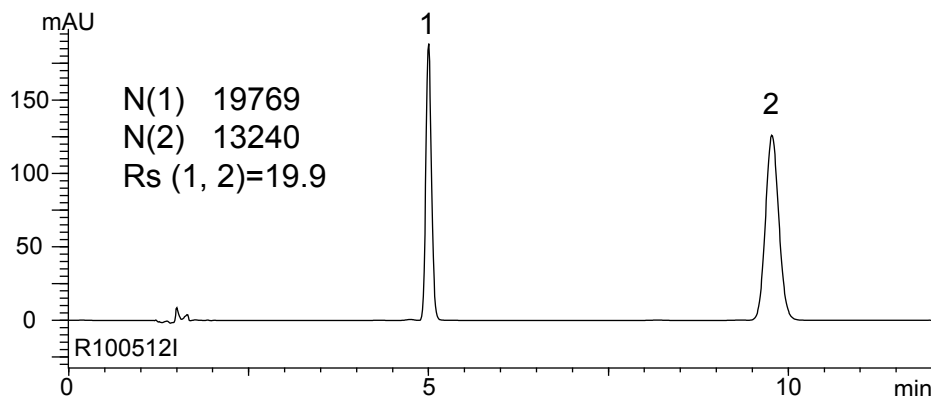
(日本薬局方収載原案記載条件)

アトルバスタチンカルシウム錠 (日本薬局方収載原案記載条件; 定量法)
- 各種C18カラムとの比較 -

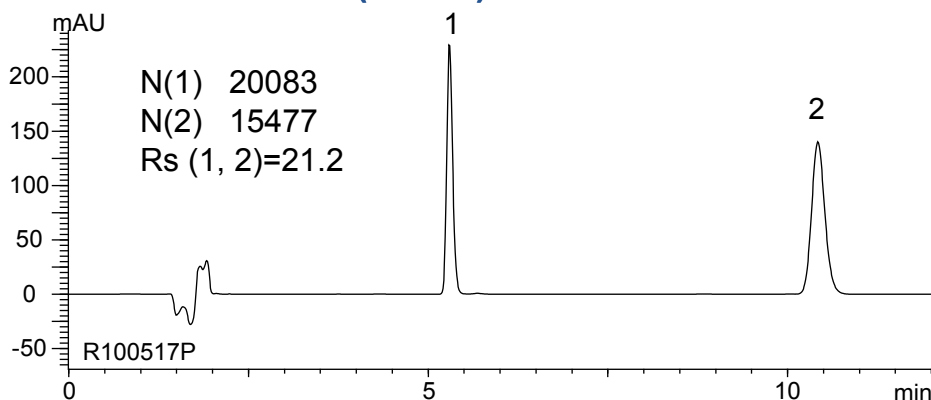
R100521A

YMC-Pack Pro C18 RS (8 nm)

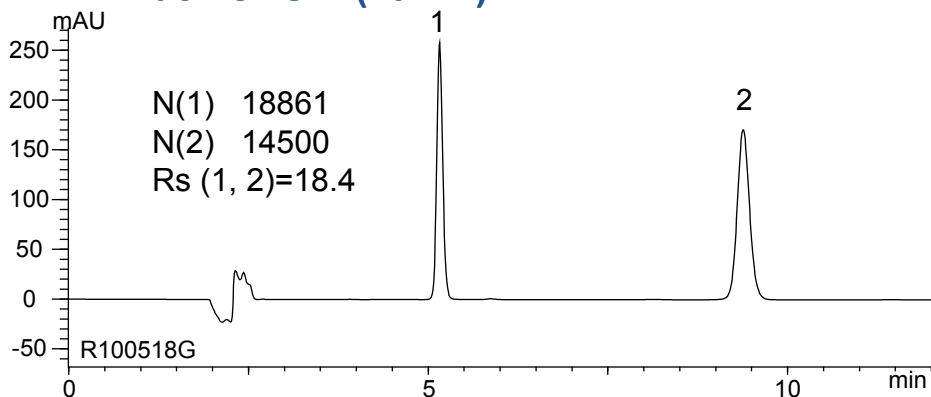
- 1,3-Dinitrobenzene (I.S.)
- Atorvastatin calcium hydrate



YMC-Pack ODS-A (12 nm)



YMC-Pack ODS-A (20 nm)



低圧で使用可能

Column : 250 X 4.6 mm I.D. (5 μm)
 Eluent : citric acid buffer*/acetonitrile/THF (53/27/20)
 ※Dissolve 10.5 g citric acid monohydrate in 900 mL water
 → adjust pH 4.0 by 28% ammonia → add water to make 1000 mL
 Temperature : 30°C
 Detection : UV at 244 nm
 Injection : 10 μL (0.04, 0.11 mg/mL)
 (日本薬局方収載原案記載条件; 定量法)