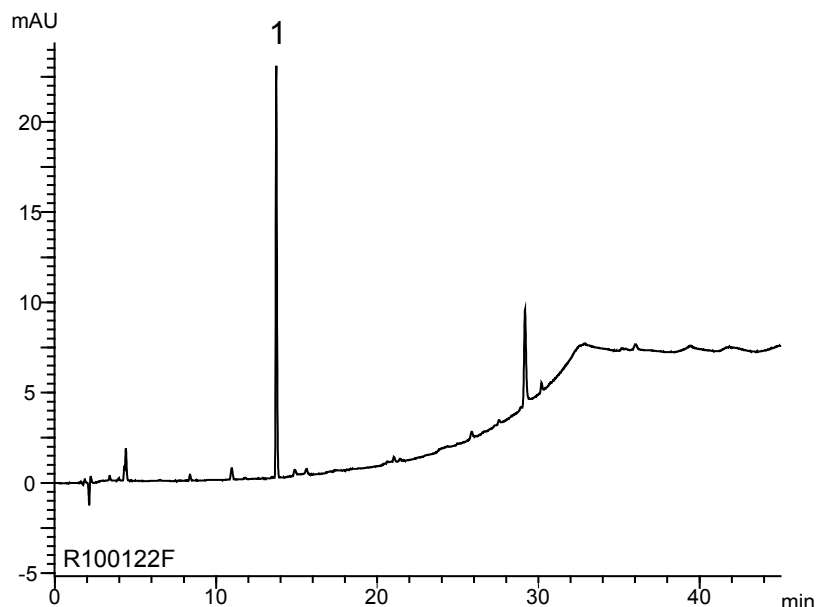
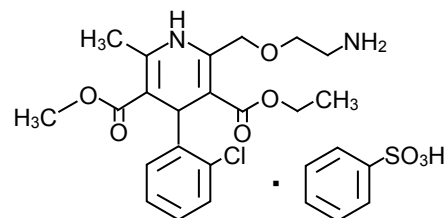


アムロジピンベシル酸塩 (第十五改正日本薬局方第一追補記載条件)
Amlodipine besilate (The Japanese Pharmacopoeia 15th Edition Supplement I) R100122G

Standard solution

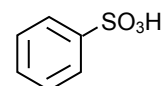


1.



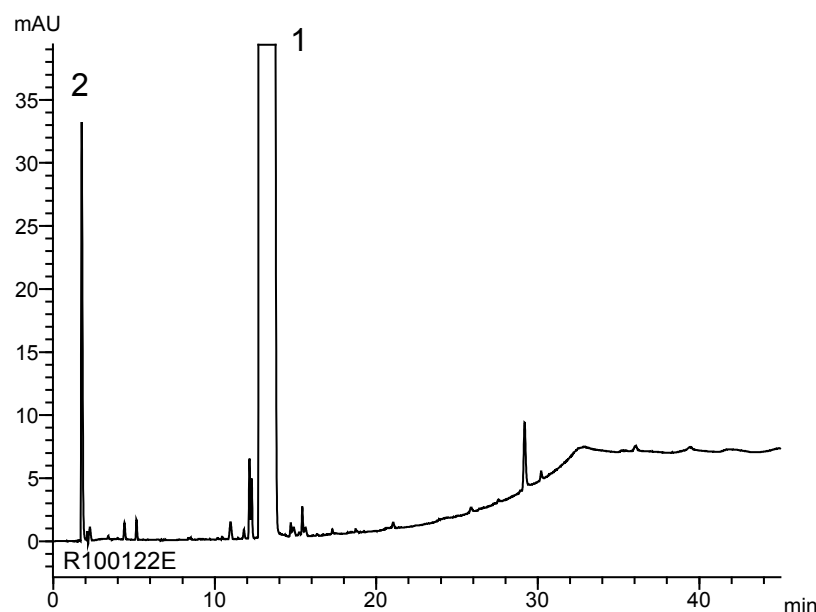
Amlodipine besilate

2.



Benzenesulfonic acid

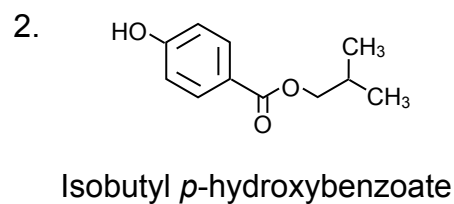
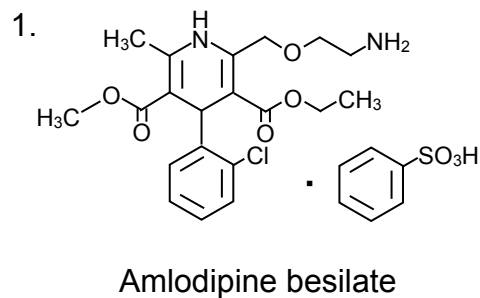
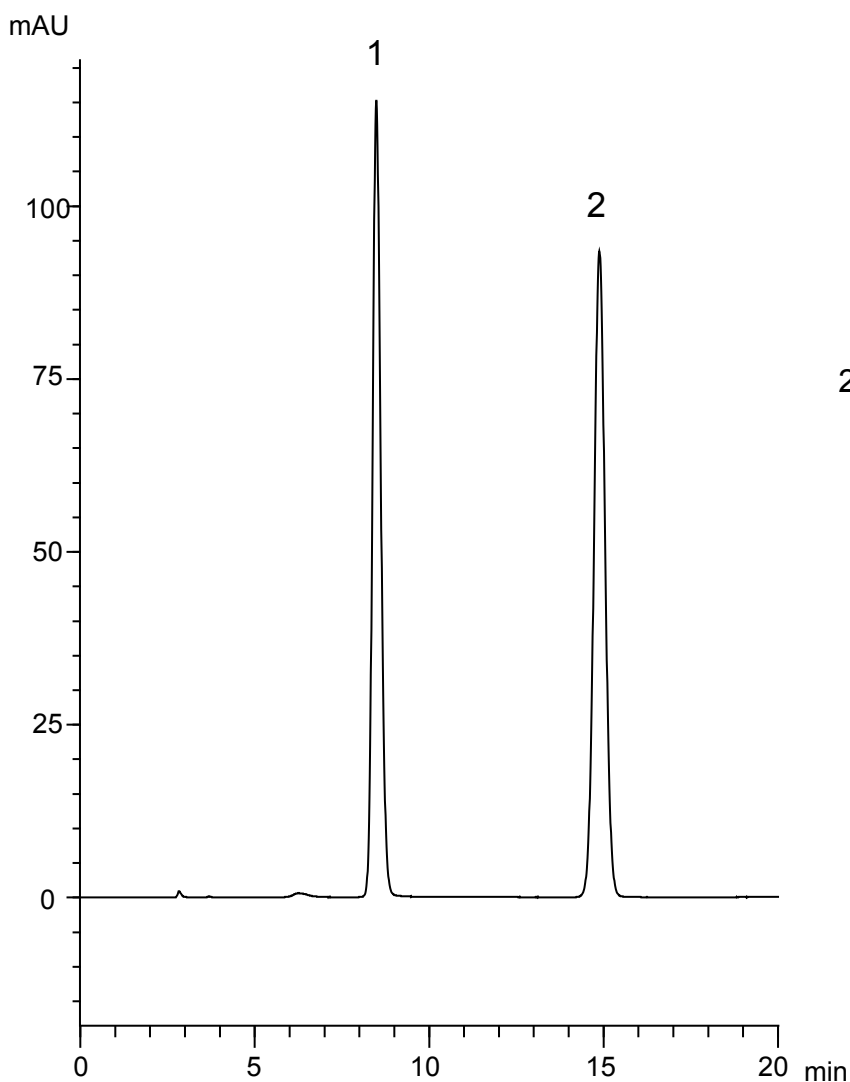
Sample solution



Column : YMC-Triart C18 (3 μm, 12 nm)
150 X 4.6 mm I.D.
Eluent : A) water/TFA (5000/1)
B) acetonitrile/TFA (5000/1)
20-80%B (0-30 min), 80%B (30-45 min)
Flow rate : 1.0 mL/min
Temperature : 35°C
Detection : UV at 237 nm
Injection : 10 μL

(第十五改正日本薬局方第一追補記載条件；純度試験)

アムロジピンベシル酸塩 (第十五改正日本薬局方第一追補記載条件)
Amlodipine besilate (The Japanese Pharmacopoeia 15th Edition Supplement I) R100127C

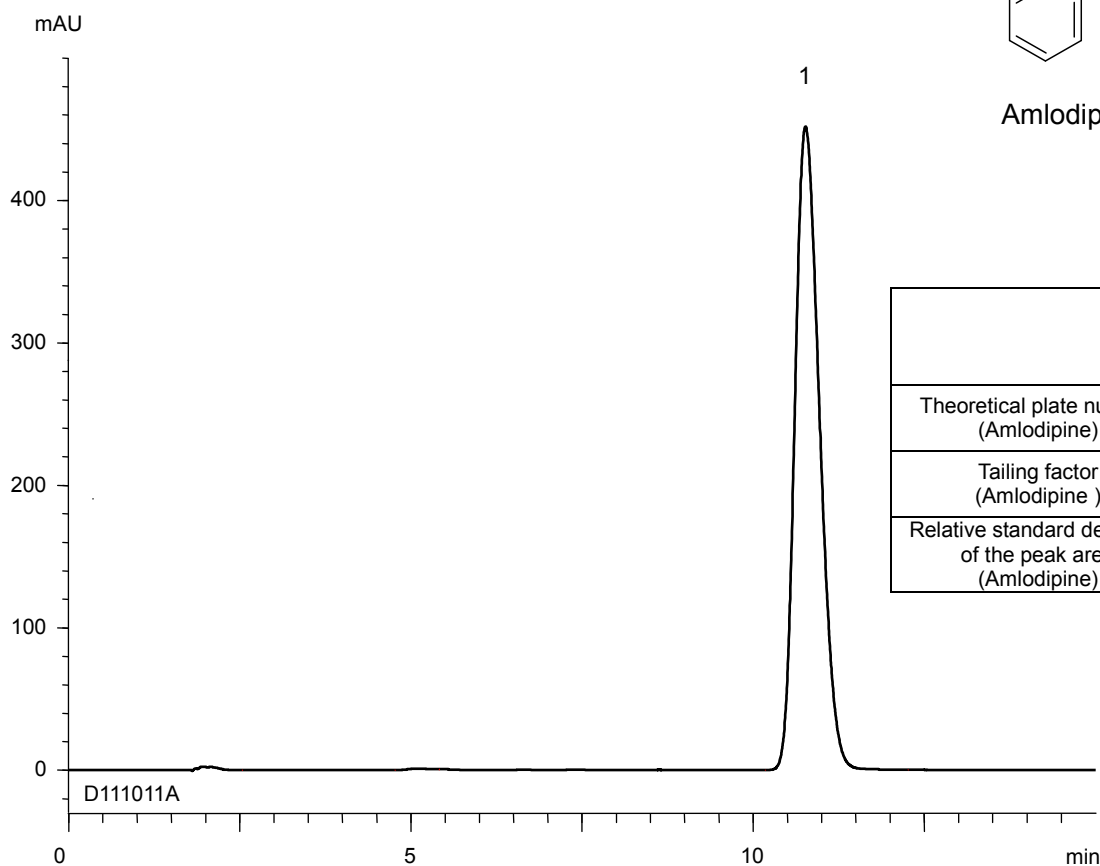
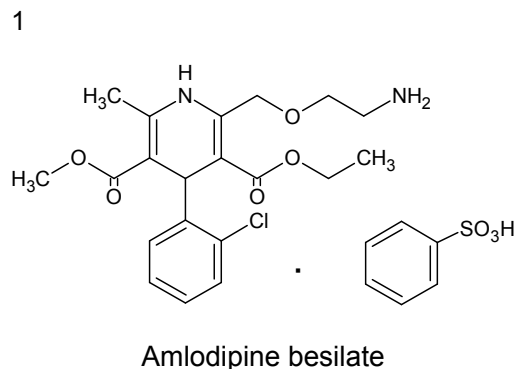


Column : YMC-Triart C18 (5 μ m, 12 nm)
150 X 4.6 mmI.D.
Eluent : methanol/ KH₂PO₄aq*(65/35)
※ Dissolve 4.1 g of KH₂PO₄ in water to make 1000 mL
Flow rate : 0.6 mL/min
Temperature : 25°C
Detection : UV at 237 nm
Injection : 20 μ L (28, 30 μ g/mL)

(第十五改正日本薬局方第一追補記載条件；定量法)

アムロジピンベシル酸塩口腔内崩壊錠
Amlodipine Besilate Orally Disintegrating Tablets

D111011A



	System suitability requirement	result
Theoretical plate number (Amlodipine)	≥ 3000	4200
Tailing factor (Amlodipine)	≤ 2.0	1.26
Relative standard deviation of the peak area (Amlodipine)	$\leq 1.0\%$	0.12%

Column : YMC-Triart C18 (5 μm , 12 nm)
150 X 4.6 mm I.D.

Eluent : phosphate buffer (pH 6.0)*/methanol (40/60)
*Dissolve 4.1 g of KH_2PO_4 in 1000 mL of water and adjust pH 6.0 with 30 mM Na_2HPO_4

Flow rate : 0.8 mL/min (adjust the flow rate so that the retention time of amlodipine is about 10 min)

Temperature : 25°C

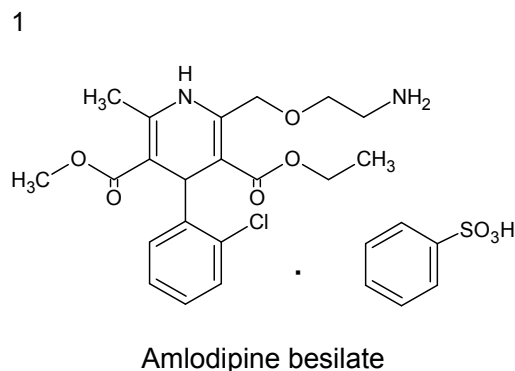
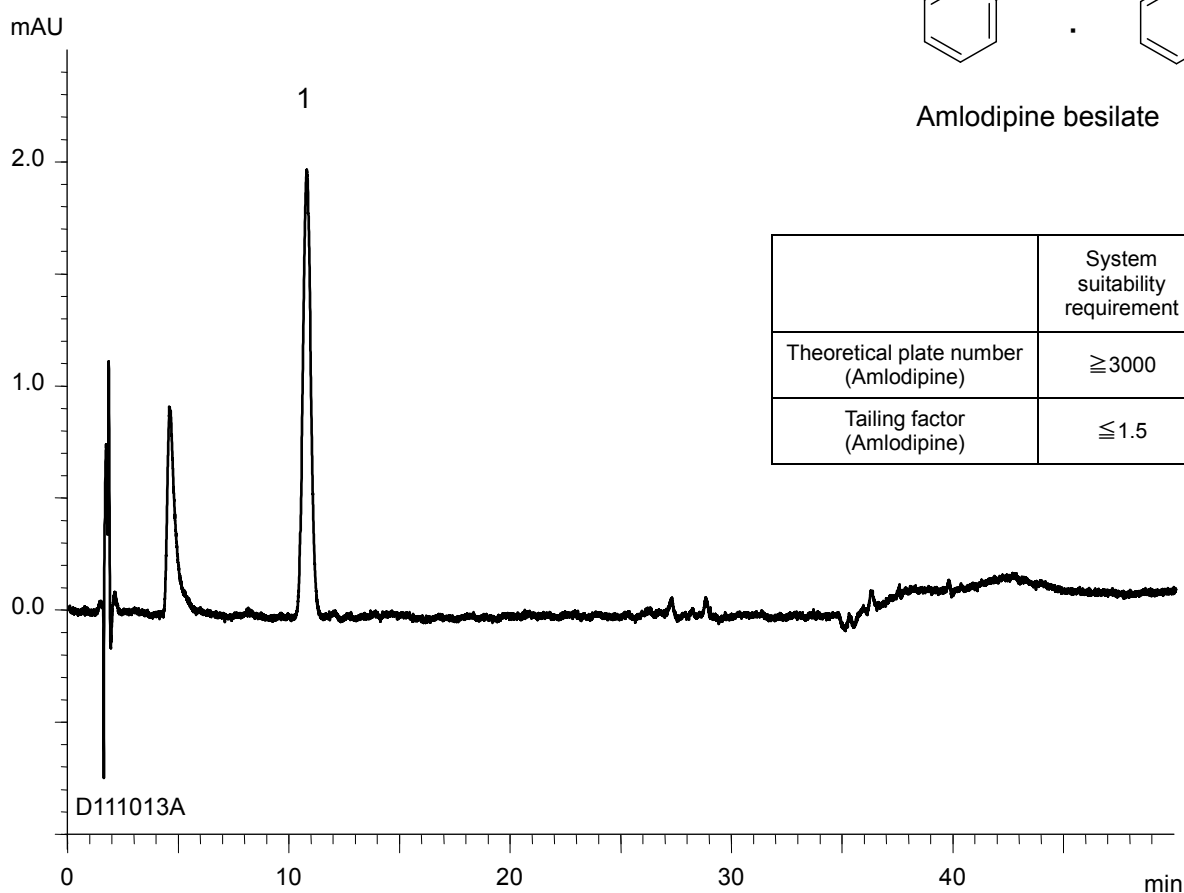
Detection : UV at 237 nm

Injection : 30 μL (0.14 mg/mL)

(The draft for the Japanese Pharmacopoeia; Assay)

アムロジピンベシル酸塩口腔内崩壊錠
Amlodipine Besilate Orally Disintegrating Tablets

D111013A



	System suitability requirement	result
Theoretical plate number (Amlodipine)	≥ 3000	4300
Tailing factor (Amlodipine)	≤ 1.5	1.09

Column : YMC-Triart C18 (5 μm, 12 nm)
150 X 4.6 mm I.D.

Eluent : A) phosphate buffer (pH 6.0)* / methanol (50/50)
B) phosphate buffer (pH 6.0)* / methanol (5/95)
20%B (0-10 min), 20-100%B (10-35 min), 100%B (35-50 min)
**Dissolve 4.1 g of KH₂PO₄ in 1000 mL of water and adjust pH 6.0 with 30 mM Na₂HPO₄*

Flow rate : 0.9 mL/min (adjust the flow rate so that the retention time of amlodipine is about 10 min)

Temperature : 25°C

Detection : UV at 237 nm

Injection : 30 μL (0.0007 mg/mL)

(The draft for the Japanese Pharmacopoeia; Related substances)