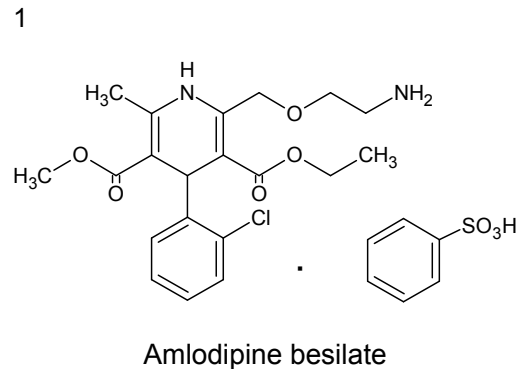
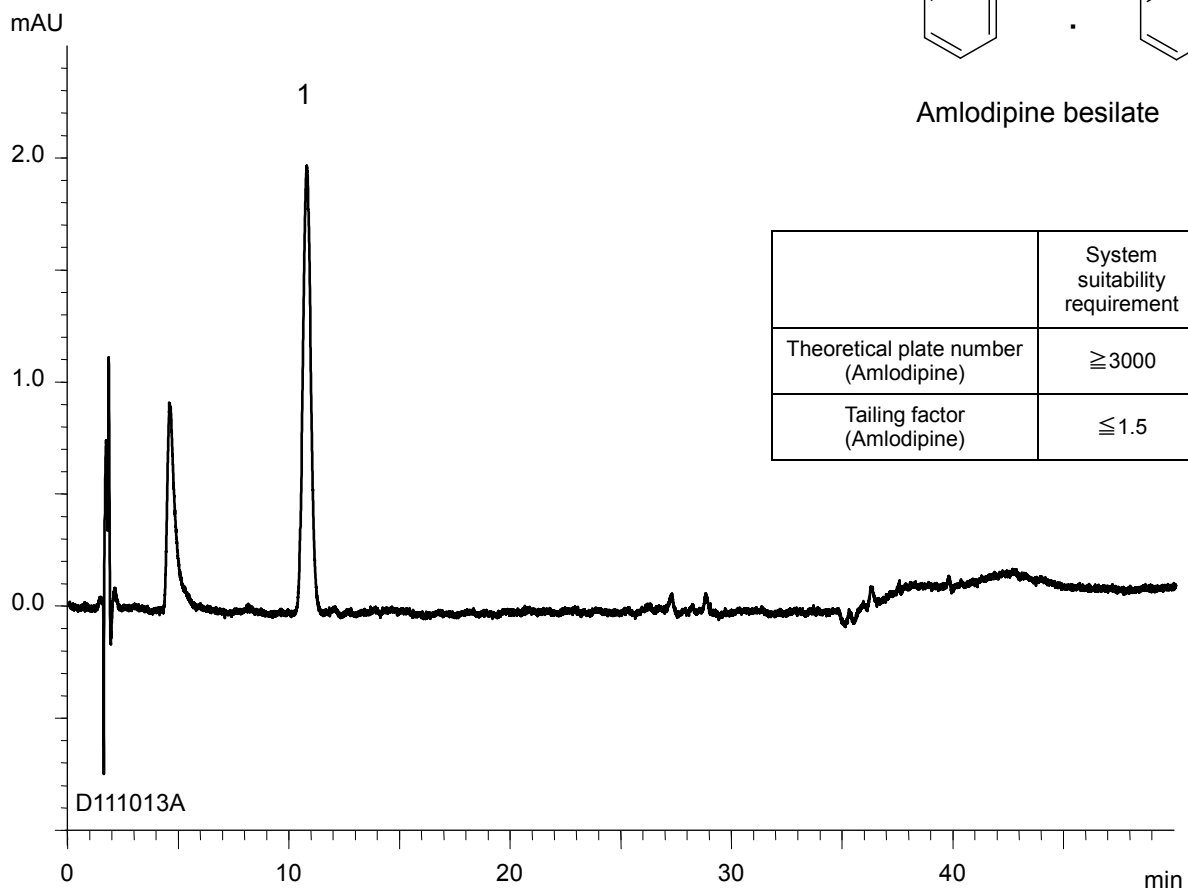


アムロジピンベシル酸塩口腔内崩壊錠
Amlodipine Besilate Orally Disintegrating Tablets

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)