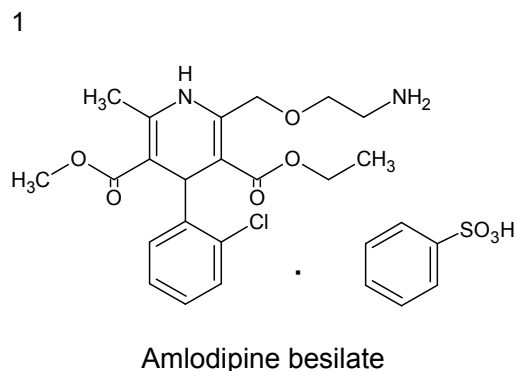
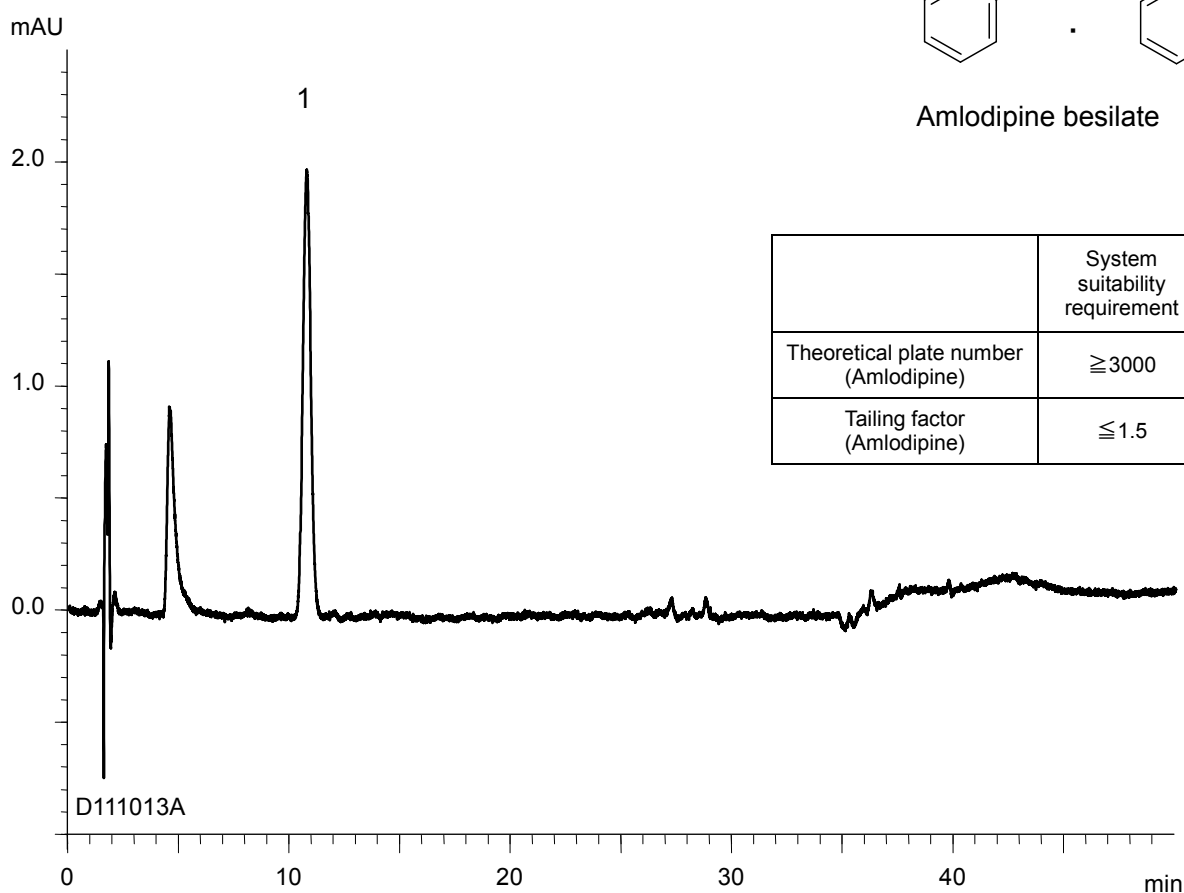


アムロジピンベシル酸塩口腔内崩壊錠  
Amlodipine Besilate Orally Disintegrating Tablets

D111013A



	System suitability requirement	result
Theoretical plate number (Amlodipine)	$\geq 3000$	4300
Tailing factor (Amlodipine)	$\leq 1.5$	1.09

Column : YMC-Triart C18 (5  $\mu$ m, 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  $\text{KH}_2\text{PO}_4$  in 1000 mL of water and adjust pH 6.0 with 30 mM  $\text{Na}_2\text{HPO}_4$*

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  $\mu$ L (0.0007 mg/mL)

(The draft for the Japanese Pharmacopoeia; Related substances)