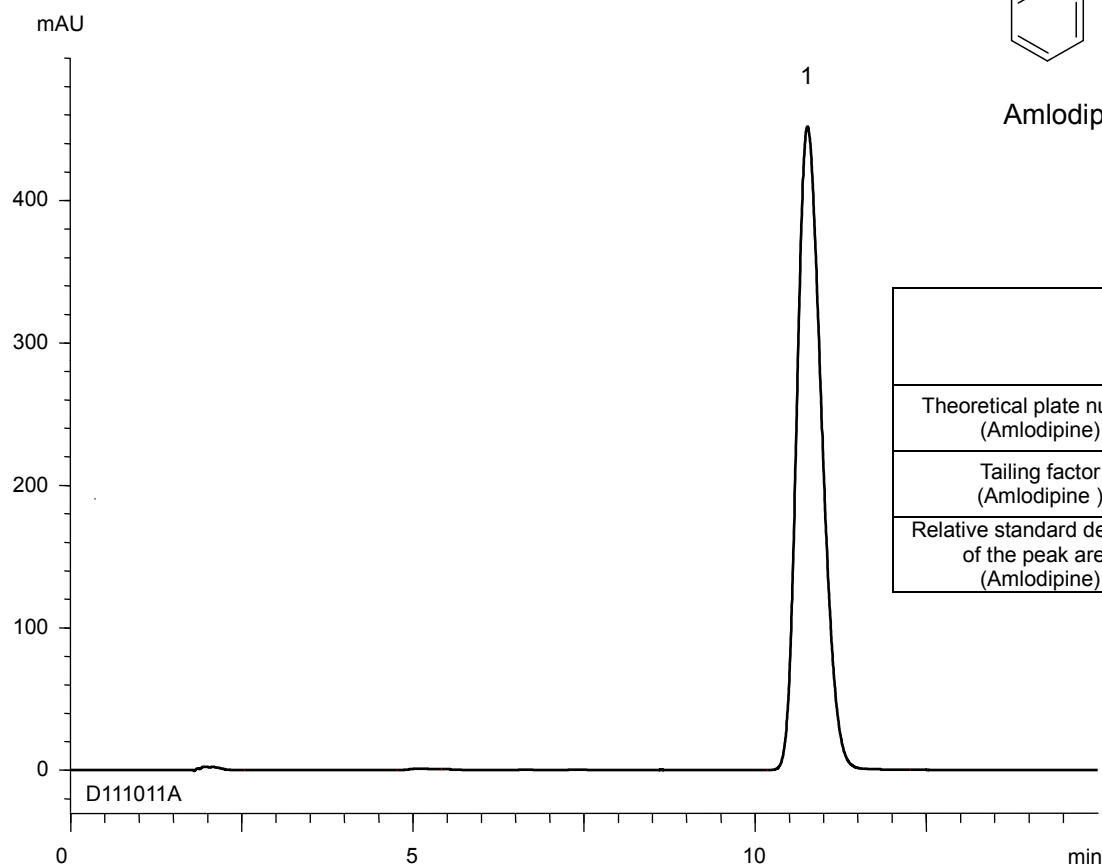
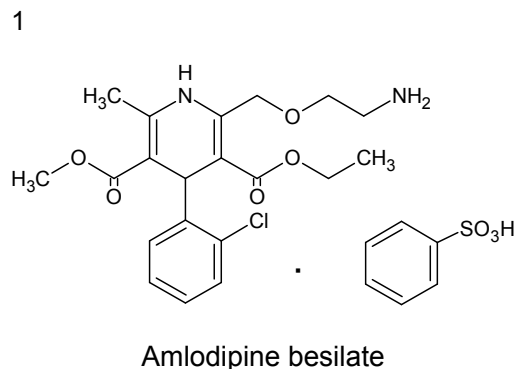


アムロジピンベシル酸塩口腔内崩壊錠  
Amlodipine Besilate Orally Disintegrating Tablets

D111011A



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

Column : YMC-Triart C18 (5  $\mu$ m, 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  $\mu$ L (0.14 mg/mL)

(The draft for the Japanese Pharmacopoeia; Assay)