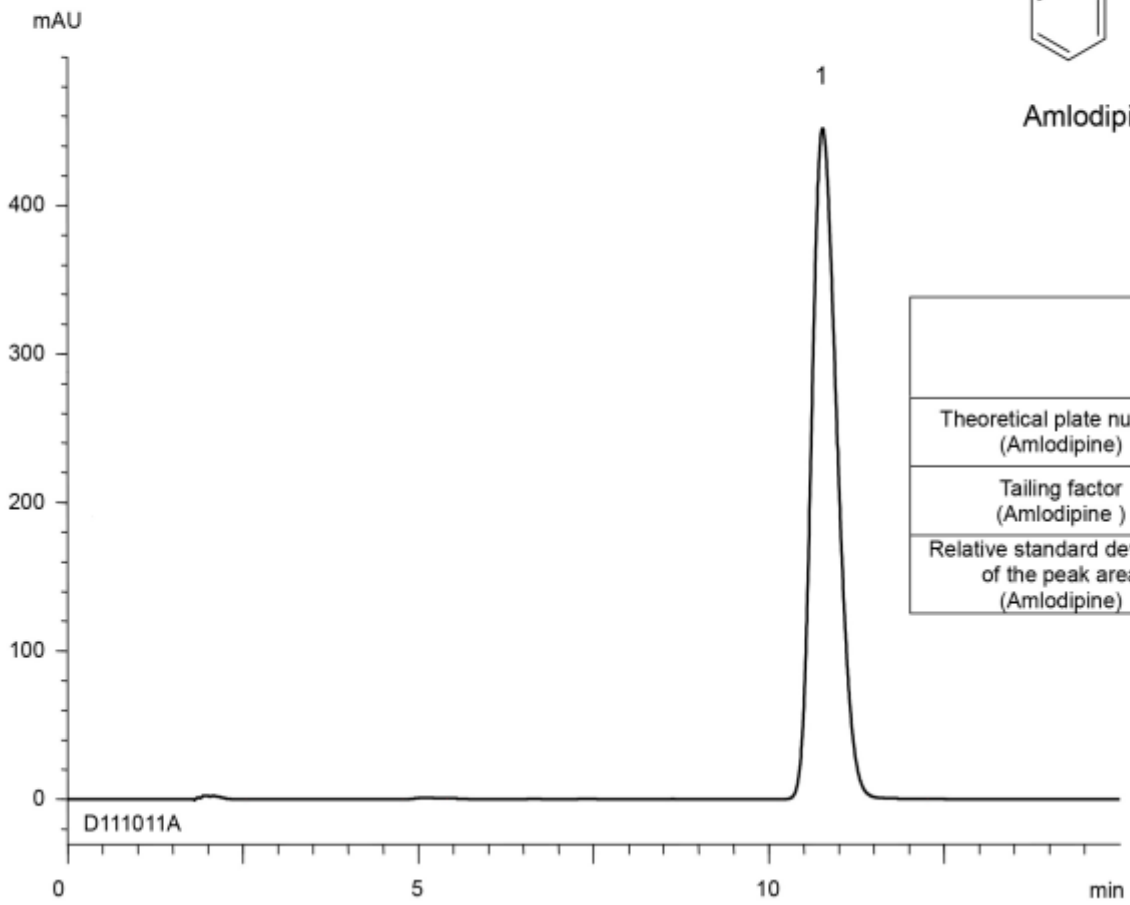

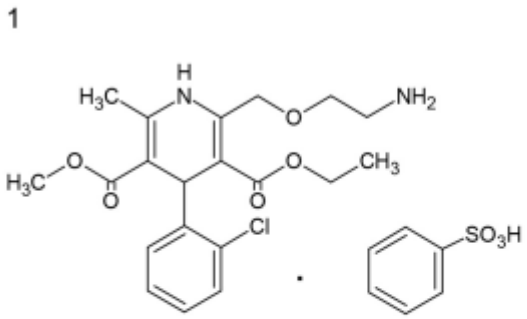

Amlodipine besilate

	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)	≦1.0%	0.12%

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