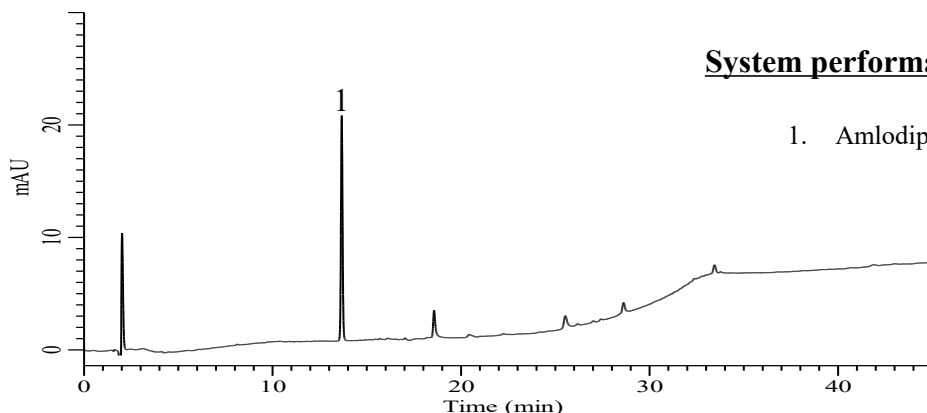


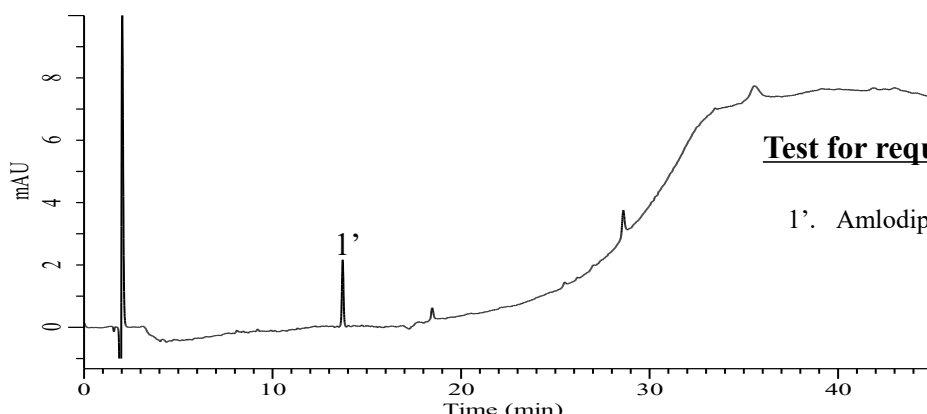
Analysis of Amlodipine Besilate

(Under the Condition of the Japanese Pharmacopoeia 18th, Amlodipine Besilate, Purity(2) Related Substances)



System performance

1. Amlodipine Besilate 6 µg/mL



Test for required detectability

1'. Amlodipine Besilate 0.6 µg/mL

Conditions

System : Chromaster PLUS (HITACHI)
Column : InertSustain C18 (GL Sciences Inc.)
 (3 µm, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020-07445
Eluent : A) 0.02% TFA in CH₃CN
 B) 0.02% TFA in H₂O

Time(min)	A(%)	B(%)
0	20	80
30	80	20
45	80	20

Flow Rate : 1.0 mL/min
Col. Temp. : 35 °C
Detection : UV 237 nm (Chromaster 5430 DAD)
Injection Vol. : 10 µL
Sample : Standard in 50% CH₃CN

Analyte:

1. Amlodipine Besilate

Number of theoretical plates of 1 : 122,503 (≥ 70,000)

Tailing factor of 1 : 1.07 (≤ 1.5)

RSD of the peak area of 1 (n=6) : 0.57 (≤ 2.0)

Test for required detectability

Peak area of 1 : 117841

Peak area of 1' : 12808

1'/1 (%) : 10.9 (7-13)