

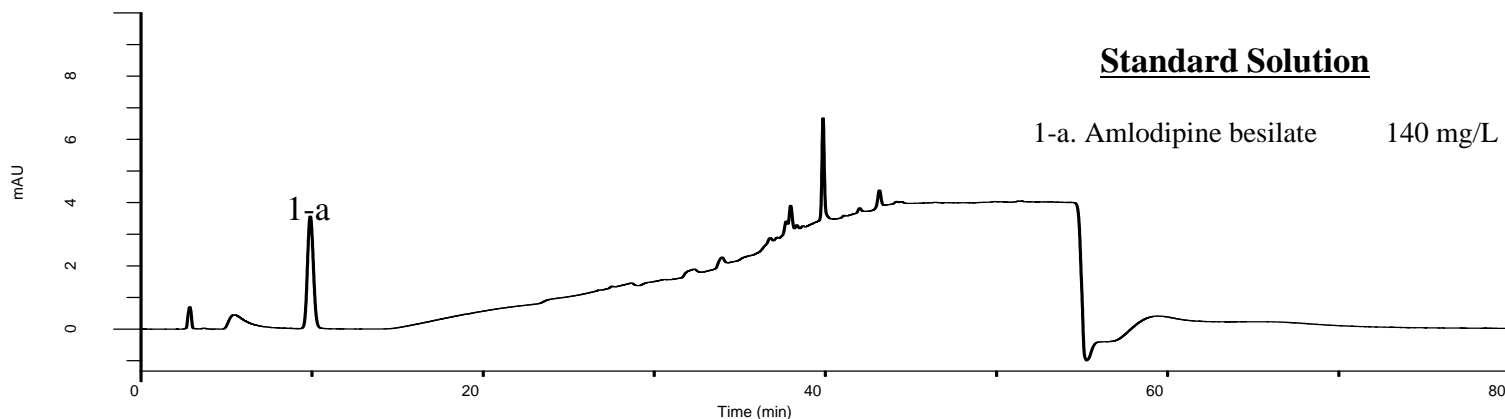
Analysis of Amlodipine besilate

(Under the Condition of the Japanese Pharmacopoeia,
Amlodipine Besilate Orally Disintegrating Tablets)

Data No. LB371-0894

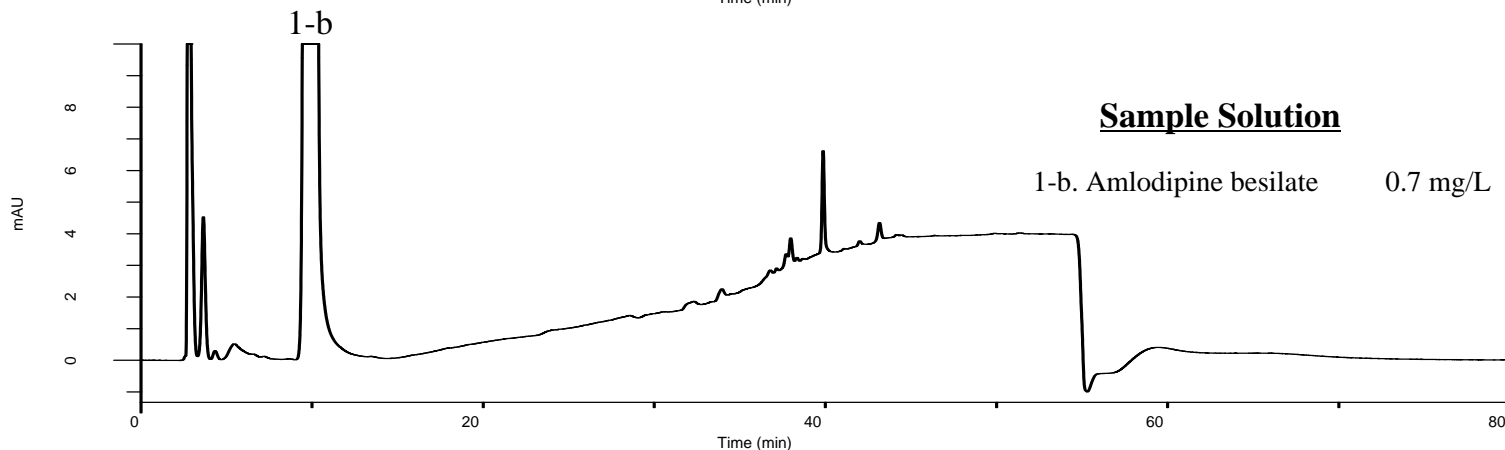
Standard Solution

1-a. Amlodipine besilate 140 mg/L



Sample Solution

1-b. Amlodipine besilate 0.7 mg/L



Conditions

System : GL7700 HPLC system
Column : InertSustainSwift C18
 (5 μ m, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020-88026
Eluent : A) CH₃OH/Buffer* = 500/500, v/v
 B) CH₃OH/Buffer* = 950/50, v/v

Analyte:

1. Amlodipine besilate

Time (min)	A (vol%)	B (vol%)
0.0	80	20
10.0	80	20
35.0	0	100
50.0	0	100
50.0	80	20
80.0	80	20

Theoretical plates : 3,955 (\geq 3,000)
 Tailing factor : 1.08 (\leq 1.5)
 RSD of the peak area (%) (n=6) : 0.11 (\leq 2.0)

Flow Rate : 0.67 mL/min
Col. Temp. : 25 °C
Detection : UV 237 nm (UV7750 UV Detector)
Injection Vol. : 30 μ L
Sample : Tablets

* Dissolve 4.1 g/L of potassium dihydrogen phosphate in 1,000 mL of water, adjust to pH 6.0 with a solution of 5.4 g of disodium hydrogen phosphate dodecahydrate in 500 mL of water.