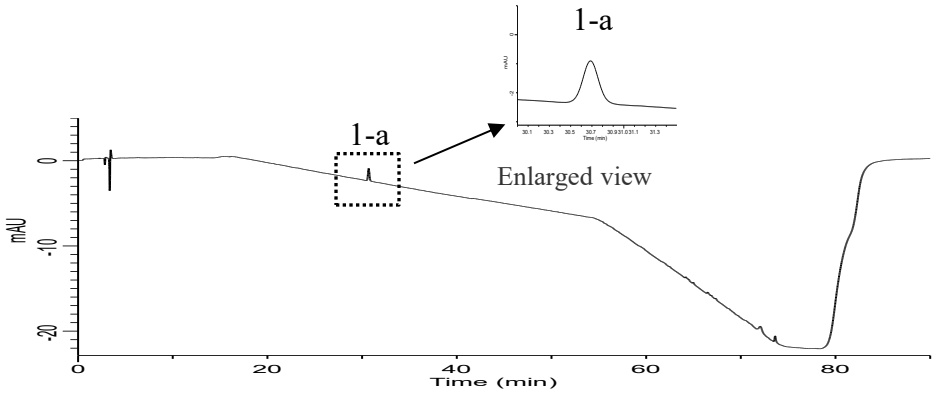
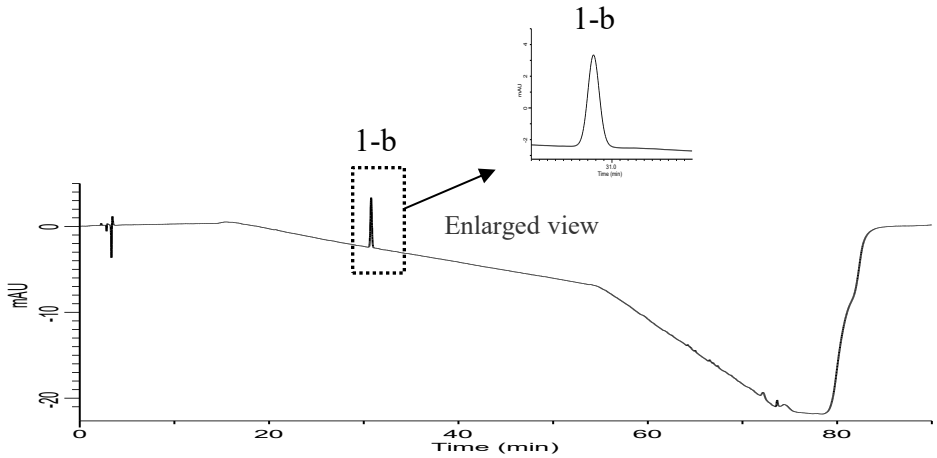
InertSearch for LC Data No. LC183-7111

Analysis of Linagliptin

(Under the Condition of draft for USP PF52(3), Linagliptin and Metformin Hydrochloride Tablets, ORGANIC IMPURITIES, LINAGLIPTIN)



Sensitivity solution



Standard solution

Conditions

System : Primaide (HITACHI)
Column : InertSustain C18 HP (GL Sciences Inc.) (3 µm, 250 x 4.6 mm I.D.)
Column Cat. No. : 5020-14426
Eluent : A) CH_3CN/H_2O＝90/10, v/v
B) CH_3CN/Solution*＝5/95, v/v

Time (min)	A (vol %)	B (vol %)
0.0	15	85
10.0	15	85
50.0	40	60
70.0	85	15
75.0	85	15
77.0	15	85
90.0	15	85

Flow Rate : 1.0 mL/min
Col. Temp. : 40 ℃
Detection : UV 227 nm (Primaide 1435 DAD)
Injection Vol. : 10 µL
Sample : Standard in CH_3CN/H_2O=40/60, v/v

*: 0.5 mL/L of TFA in water

Analyte:

1-a. Linagliptin	0.25 µg/mL
1-b. Linagliptin	1.0 µg/mL

Signal-to-noise ratio (1-a) : 20.7 (≧ 10)

RSD of
the peak area (%)(n=6)(1-b) : 0.74 (≦ 5.0)