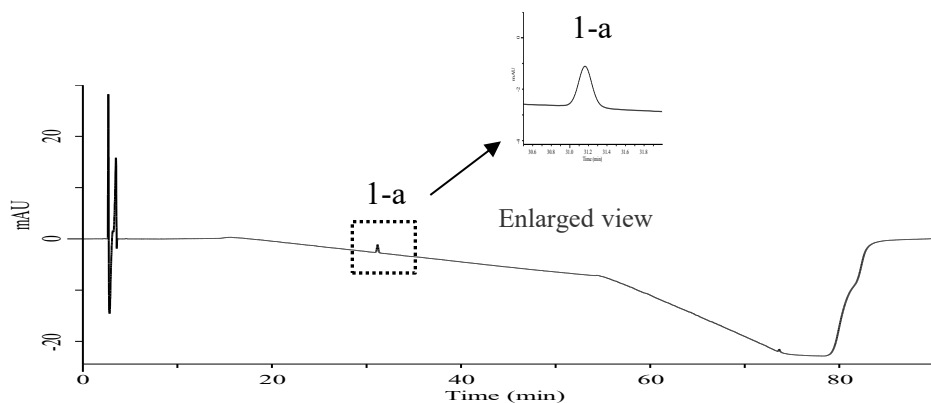
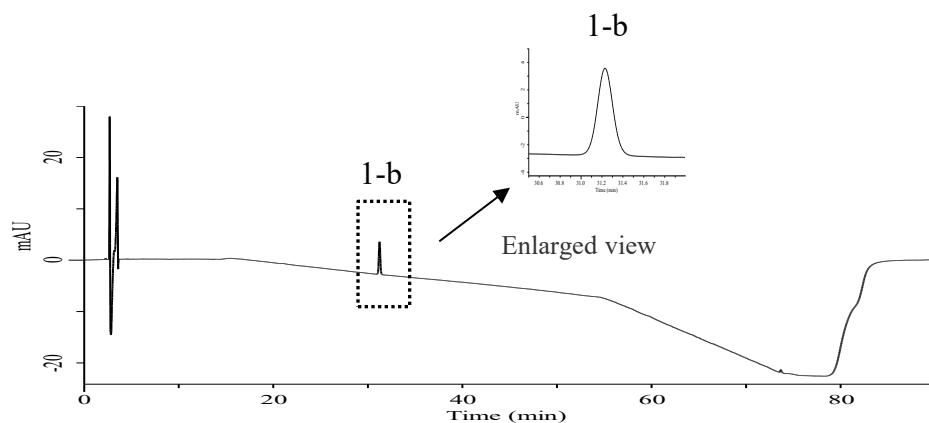


Analysis of Linagliptin

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



Sensitivity solution



Standard solution

Conditions

System : Primaide (HITACHI)
Column : InertSustain C18 HP (GL Sciences Inc.)
(3 μ m, 250 x 4.6 mm I.D.)
Column Cat. No. : 5020-14446
Eluent : A) CH₃CN/H₂O=90/10, v/v
B) CH₃CN/Solution*=5/95, v/v

Analyte:

1-a. Linagliptin 0.25 μ g/mL
1-b. Linagliptin 1.0 μ g/mL

Signal-to-noise ratio (1-a) : 18.8 (≥ 10)

RSD of
the peak area (%) (n=6) (1-b) : 0.56 (≤ 5.0)

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 $^{\circ}$ C
Detection : UV 227 nm (Primaide 1435 DAD)
Injection Vol. : 10 μ L
Sample : Standard in CH₃OH/H₂O=60/40, v/v

*: 0.5 mL/L of TFA in water