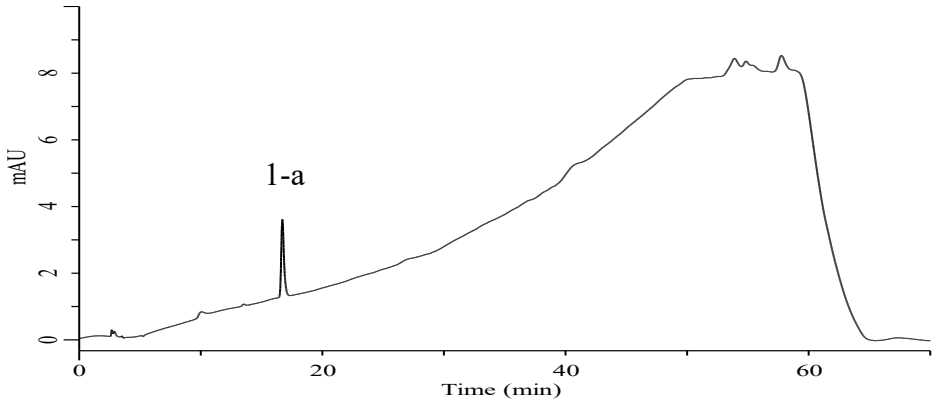
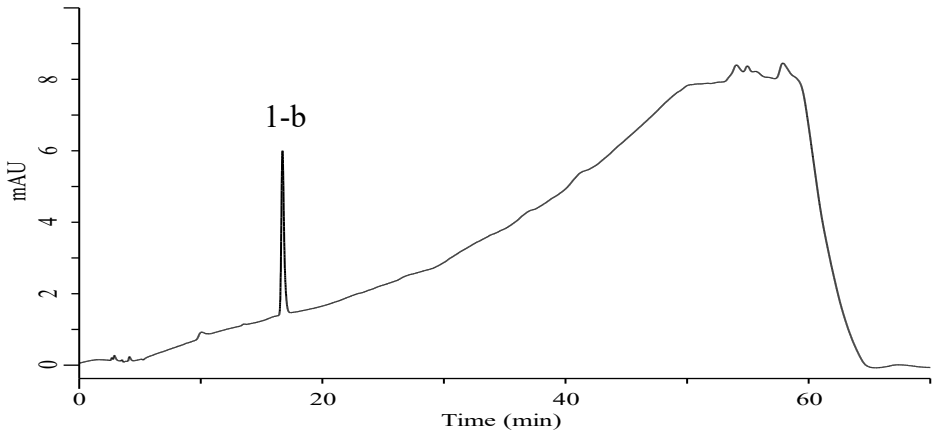
Analysis of Linagliptin

(Under the Condition of draft for USP PF52(3), Linagliptin, ORGANIC IMPURITIES, PROCEDURE 2)



Sensitivity solution



Standard solution

Conditions

System : Chromaster PLUS (HITACHI)
Column : InertSustain C18 (GL Sciences Inc.)
(5 µm, 250 x 4.6 mm I.D.)
Column Cat. No. : 5020-07346
Eluent : A) $CH_3OH/CH_3CN/H_2O$＝70/10/20, v/v/v
B) CH_3OH/Buffer*＝10/90, v/v

Time (min)	A (vol %)	B (vol %)
0.0	30	70
12.0	50	50
45.0	85	15
55.0	85	15
60.0	30	70
70.0	30	70

Flow Rate : 1.0 mL/min
Col. Temp. : 45 ℃
Detection : UV 225 nm (Chromaster 5410AD UV)
Injection Vol. : 20 µL
Sample : Standard in CH_3OH/H_2O ＝40/60, v/v

Analyte:

1-a. Linagliptin	0.25 µg/mL
1-b. Linagliptin	0.50 µg/mL

Signal-to-noise ratio (1-a) : 15.1 (≧ 10)

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

*: Dissolve 2.04 g of potassium phosphate, monobasic in 1000 mL of water. Adjust with 10% H_3PO_4 in H_2O to a pH of 3.2.