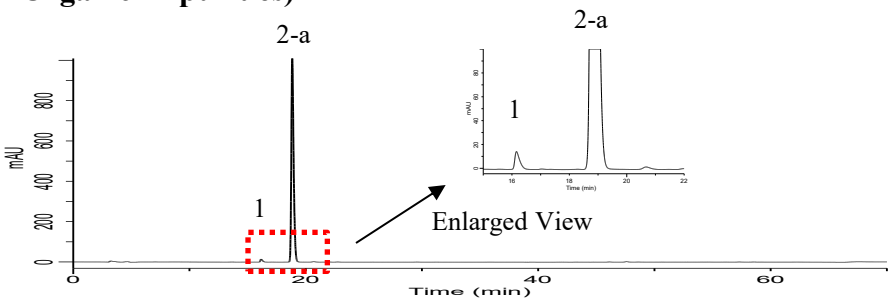
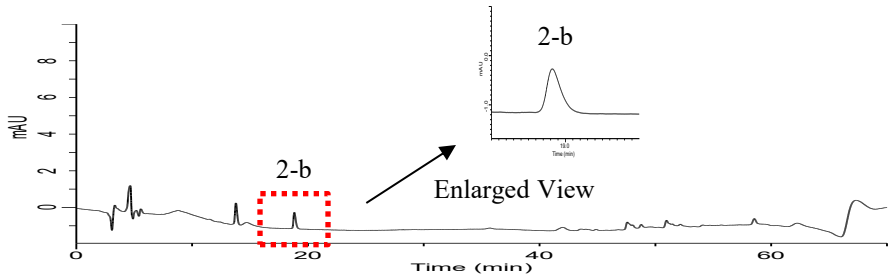
Analysis of L-thyroxine

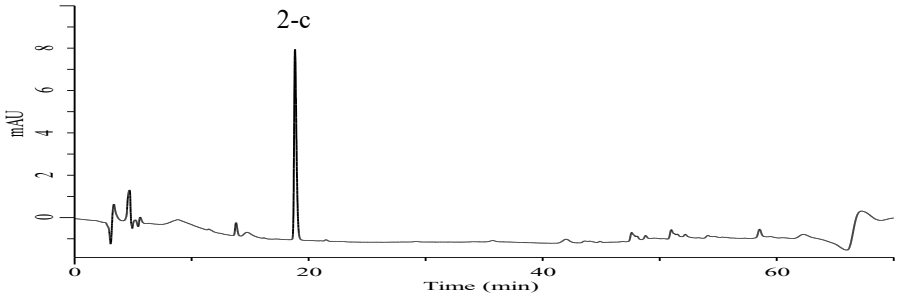
(Under the Condition of draft for USP PF52(1), Levothyroxine Sodium for Injection, Organic Impurities)



System Suitability Solution



Sensitivity Solution



Standard Solution

Conditions

System : Chromaster PLUS (HITACHI)
Column : InertSustain C18 (GL Sciences Inc.)
(3.5 µm, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020-89996
Eluent : A) CH_3CN/H_2O=90/10, v/v
B) Solution*

Time (min)	A (vol %)	B (vol %)
0.0	20	80
10.0	45	55
30.0	45	55
50.0	80	20
58.0	80	20
60.0	20	80
70.0	20	80

Flow Rate : 0.5 mL/min
Col. Temp. : 45 °C
Detection : UV 225 nm (Chromaster 5420 UV-VIS)
Injection Vol. : 100 µL
Sample : Standard

Analyte:

1. 3,3',5-Triiodo-L-thyronine	0.2 µg/mL
2-a. L-Thyroxine	20 µg/mL
2-b. L-Thyroxine	0.02 µg/mL
2-c. L-Thyroxine	0.2 µg/mL

Resolution(1, 2-a) : 7.8 (≧ 5)

RSD of the
peak area(2-c)(%)(n=6) : 1.49 (≦ 5.0)

Signal-to-noise ratio(2-b) : 16.2 (≧10)

Relative retention times
3,3',5-Triiodo-L-thyronine : 0.856
L-Thyroxine : 1.0

* : Dissolve 1.36 g of potassium phosphate, monobasic in 1000 mL of water. Adjust with 20% H_3PO_4 solution to a pH of 3.5.