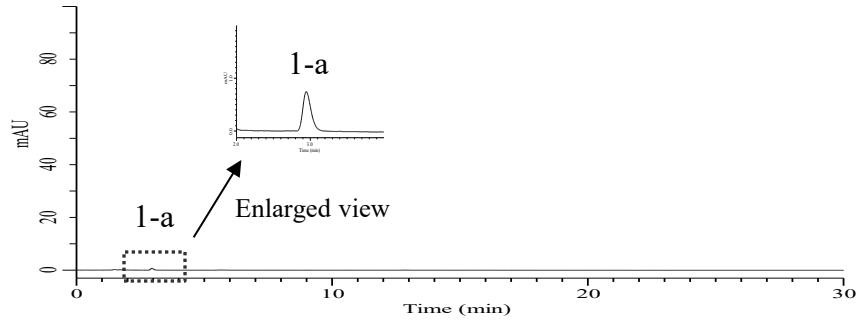
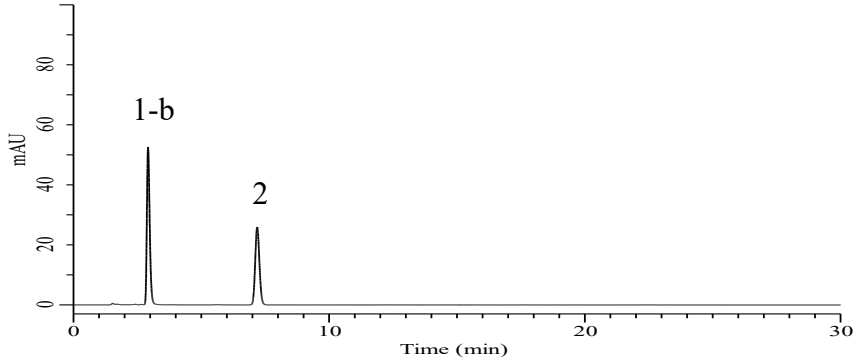
Analysis of Solifenacin succinate

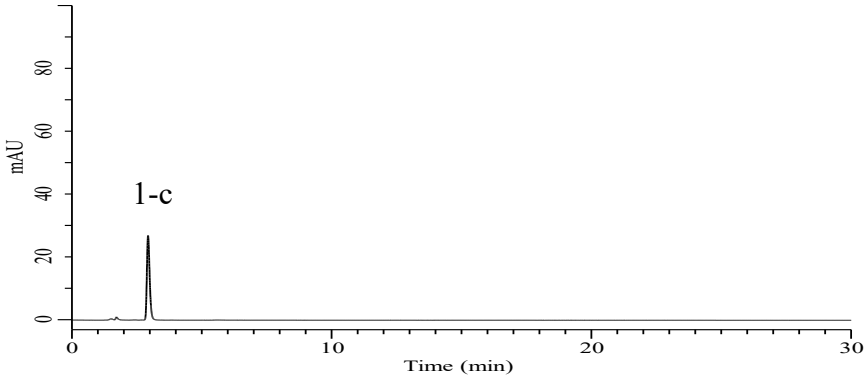
(Under the Condition of draft for the Japanese Pharmacopoeia, Solifenacin Succinate, Purity(1), Related Substances 1)



Test for required detectability



System suitability solution



Standard solution

Conditions

System	:	Primaide (HITACHI)
Column	:	InertSustain C18 (GL Sciences Inc.) (5 µm, 150 x 4.6 mm I.D.)
Column Cat. No.	:	5020-07345
Eluent	:	CH_3CN/Buffer*=50/50 , v/v
Flow Rate	:	0.8 mL/min
Col. Temp.	:	40 °C
Detection	:	UV 210 nm (Primaide 1410 UV)
Injection Vol.	:	10 µL
Sample	:	Standard

Analyte:

1-a. Solifenacin succinate	0.15 µg/mL
1-b. Solifenacin succinate	10 µg/mL
1-c. Solifenacin succinate	5 µg/mL
2. Benzyl *p*-Hydroxybenzoate	5 µg/mL

Test for required detectability (%) : (2 ≦) 2.6 (≦ 4)

Resolution (1-b, 2) : 16.9 (≧ 10)

RSD of
the peak area of 1-c (%)(n=6) : 0.34 (≦ 2.0)

* : Dissolve 8.7 g of dipotassium hydrogenphosphate in water to make 1000mL, and adjust to pH 6.0 with phosphoric acid.