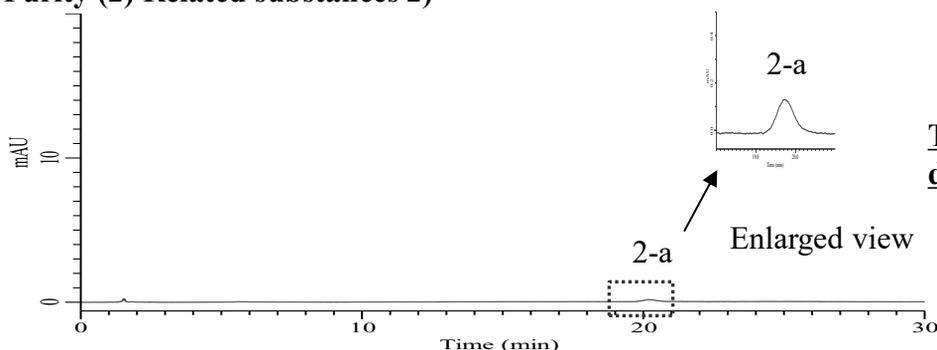
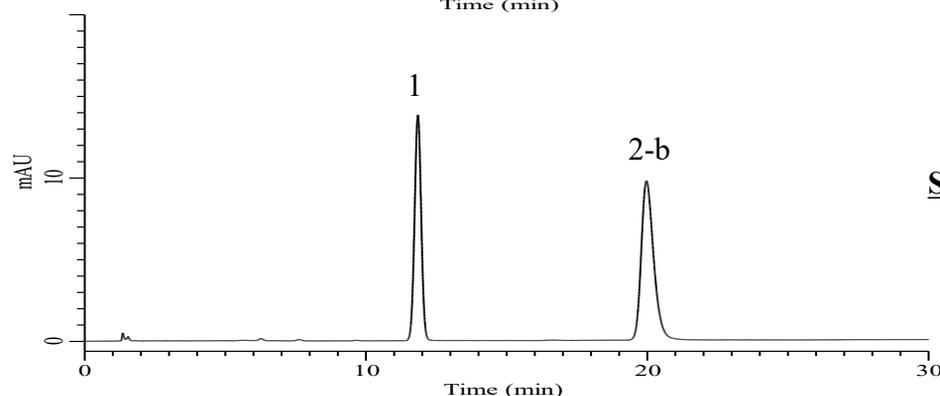


Analysis of Solifenacin succinate

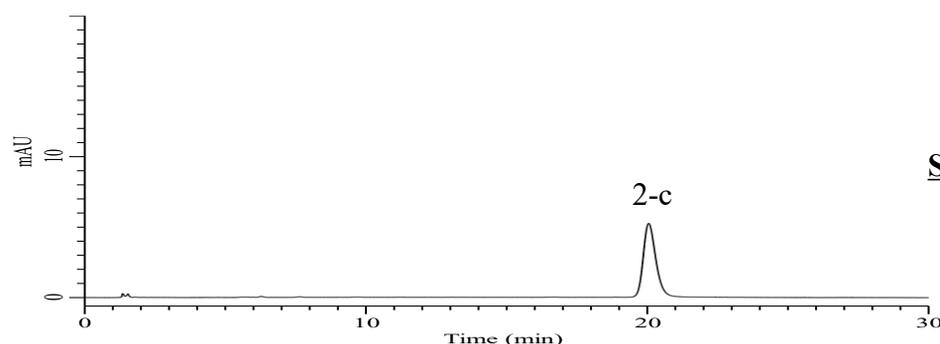
(Under the Condition of draft for the Japanese Pharmacopoeia , Solifenacin Succinate, Purity (2) Related substances 2)



Test for required detectability



System suitability solution



Standard solution

Conditions

System : Primaide (HITACHI)
Column : InertSustain AQ-C18 (GL Sciences Inc.)
 (5 μm, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020-89730
Eluent : CH₃CN/Buffer*=30/70 , v/v
Flow Rate : 1.0 mL/min
Col. Temp. : 40 °C
Detection : UV 210 nm (Primaide 1410 UV)
Injection Vol. : 10 μL
Sample : Standard in Eluent

Analyte:

| | |
|------------------------------------|------------|
| 1. Ethyl <i>p</i> -Hydroxybenzoate | 5 μg/mL |
| 2-a. Solifenacin Succinate | 0.15 μg/mL |
| 2-b. Solifenacin Succinate | 10 μg/mL |
| 2-c. Solifenacin Succinate | 5 μg/mL |

Test for required detectability (2-a) (%) : (2 ≤) 2.9 (≤ 4)

Resolution : 13.3 (≥ 10)

RSD of the peak area of 2-c (%) (n=6) : 0.40 (≤ 3.5)

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