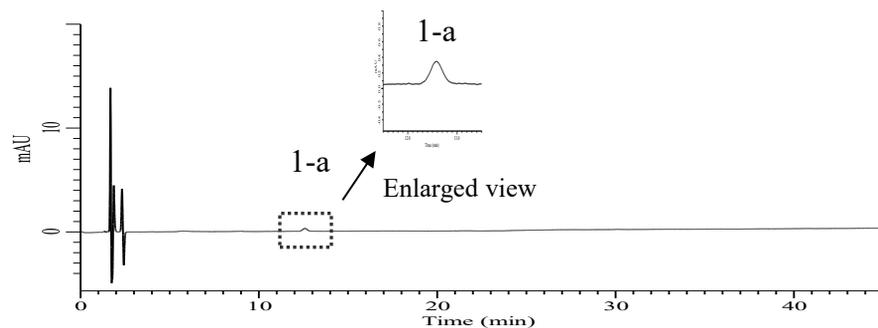
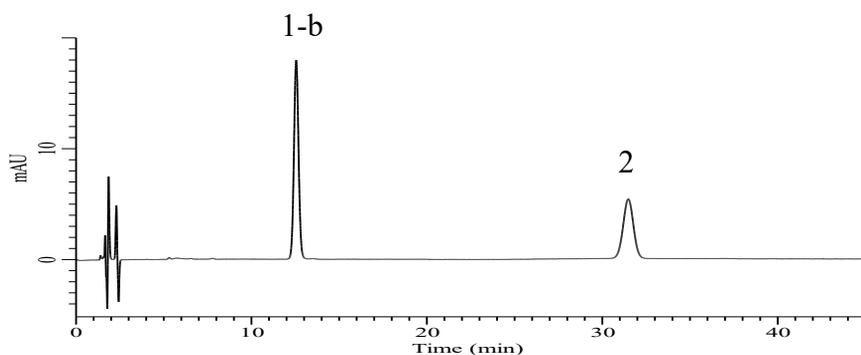


Analysis of Solifenacin succinate

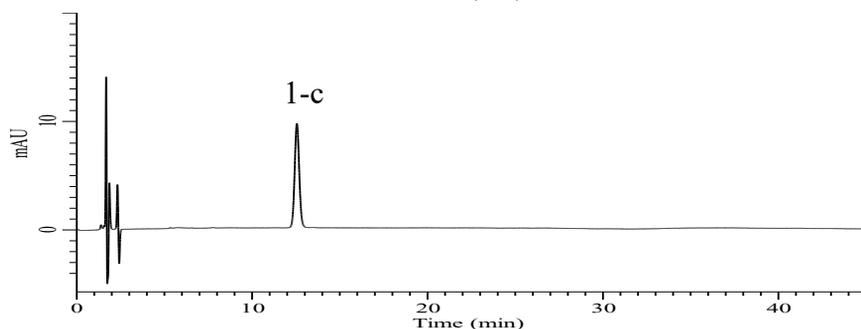
(Under the Condition of draft for the Japanese Pharmacopoeia , Solifenacin Succinate, Purity (3) Related substances 3)



Test for required detectability



System suitability solution



Standard solution

Conditions

System : Primaide (HITACHI)
Column : Inertsil ODS-4 (GL Sciences Inc.)
 (5 μm, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020-03945
Eluent : 2-Propanol/CH₃CN/CH₃OH/Buffer*=10/20/5/65 , v/v/v/v
Flow Rate : 1.0 mL/min
Col. Temp. : 40 °C
Detection : UV 210 nm (Primaide 1435 DAD)
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 (1-a) (%) : (2 ≤) 2.8 (≤ 4)

Resolution (1-b, 2) : 24.3 (≥ 10)

RSD of the peak area of 1-c (%) (n=6) : 0.39 (≤ 3.0)

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