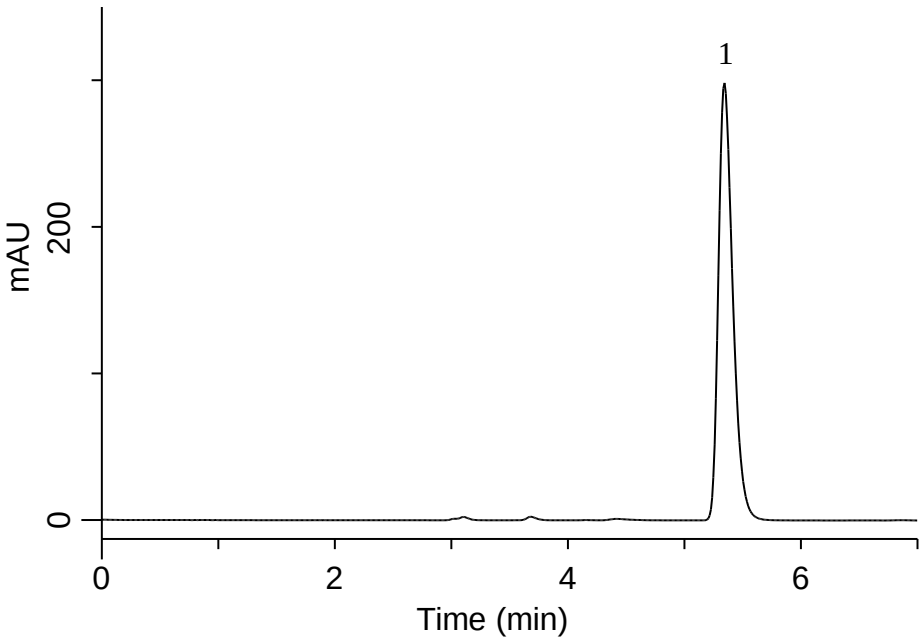
Analysis of Solifenacin Succinate

(Under the Condition of the draft for USP)



Conditions

System : GL7700 HPLC system
Column : Inertsil Ph
(5 μm, 250 x 4.6 mmI.D.)
Column Cat. No. : 5020-01328
Eluent : A) CH_3CN
B) CH_3OH
C) Buffer※
A/B/C = 30/30/40, v/v/v
Flow Rate : 1.0 mL/min
Col. Temp. : 30 ℃
Detection : UV 220 nm (PD7752 PDA Detector)
Injection Vol. : 10 μL
Sample : Standard

※Dissolve 4.1 g of monobasic potassium phosphate in 1 L of water and add 2 mL of triethylamine.
Adjust pH 2.5 with phosphoric acid.

Analyte:

1. Solifenacin Succinate 0.2 mg/mL

Tailing factor	: 1.39 (≦ 2.0)
RSD of the area (%) (n=5)	: 0.26 (≦ 0.73)