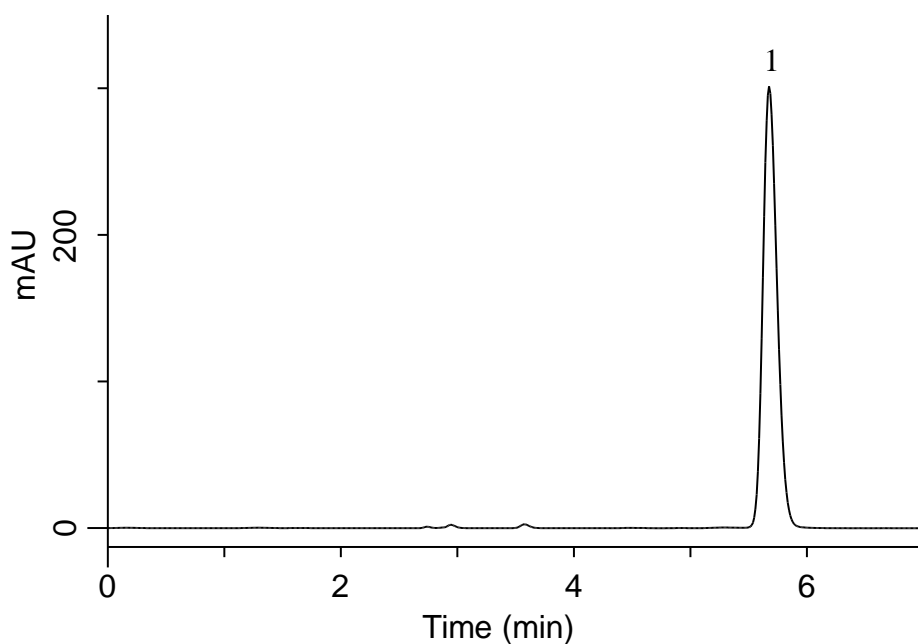


Analysis of Solifenacin Succinate

(Under the Condition of the draft for USP)



Conditions

System : GL7700 HPLC system
Column : InertSustain Phenylhexyl
 (5 μ m, 250 x 4.6 mmI.D.)
Column Cat. No. : 5020-89027
Eluent : A) CH₃CN
 B) CH₃OH
 C) Buffer*
 A/B/C = 30/30/40, v/v/v
Flow Rate : 1.0 mL/min
Col. Temp. : 30 °C
Detection : UV 220 nm (PD7752 PDA Detector)
Injection Vol. : 10 μ L
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 : 1.22 (\leq 2.0)
 RSD of the area (%) (n=5) : 0.13 (\leq 0.73)