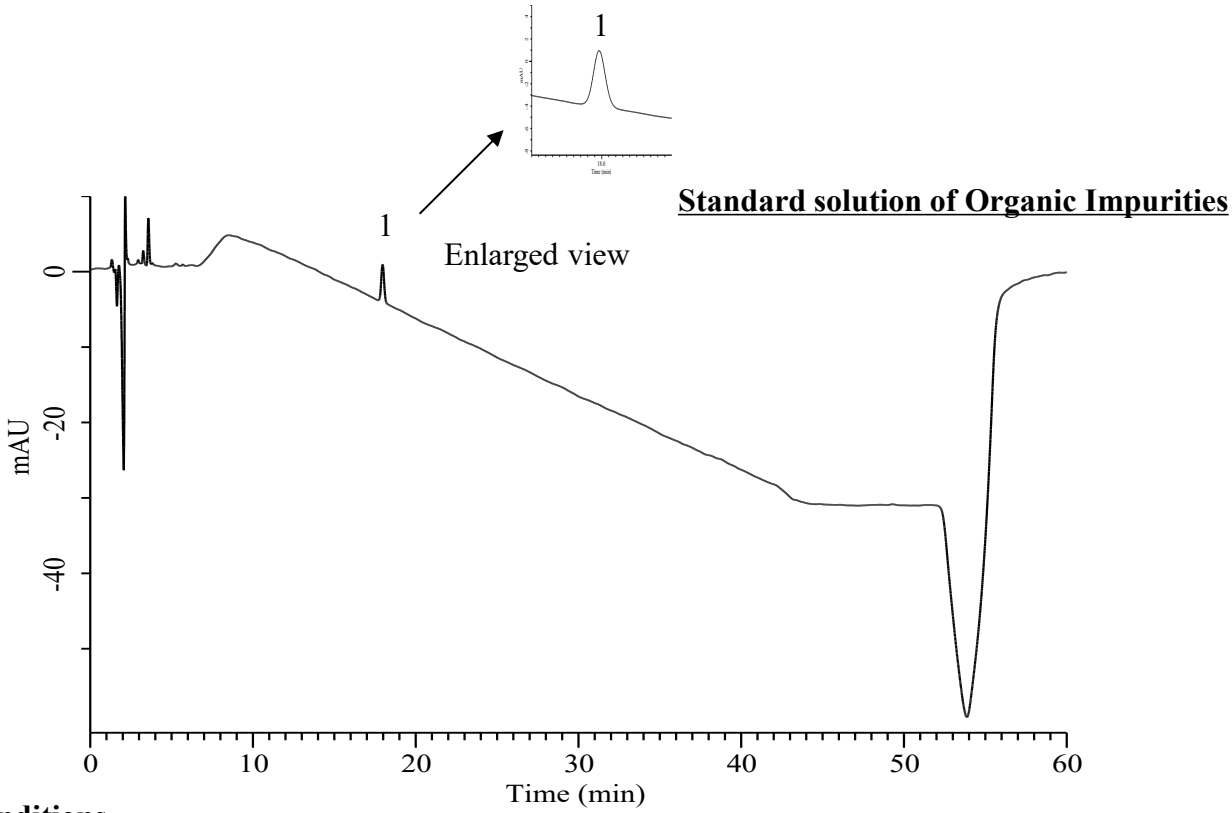
InertSearch for LC Data No. LB900-7111

Analysis of Fesoterodine Fumarate

(Under the Condition of the draft for USP, Fesoterodine Fumarate Extended-Release Tablets)



Conditions

System : Chromaster HPLC system (HITACHI)
Column : InertSustain C8 (GL Sciences Inc.)
(5 μm, 250 x 4.6 mm I.D.)
Column Cat. No. : 5020-16028
Eluent : A) CH_3CN/Buffer* = 80/20 , v/v
B) CH_3CN/Buffer* = 20/80 , v/v

Time (min)	A (vol %)	B (vol %)
0	8	92
4	8	92
40	45	55
50	45	55
51	8	92
60	8	92

Flow Rate : 1.8 mL/min
Col. Temp. : 45 ℃
Detection : UV 220 nm
Injection Vol. : 100 μL
Sample : Standard

Analyte:

1. Fesoterodine fumarate 0.75 μg/mL

RSD of the peak area (%)(n=6) : 0.88 (≦ 5.0)

Signal-to-noise ratio : 13.2 (≧ 10)

* : Transfer 1.36 g of potassium phosphate, monobasic into a 1-L volumetric flask and dissolve in 800 mL of water. Add 4.0 mL of triethylamine to the solution and dilute with water to volume. Adjust with phosphoric acid and water (10:90) to a pH of 2.8.