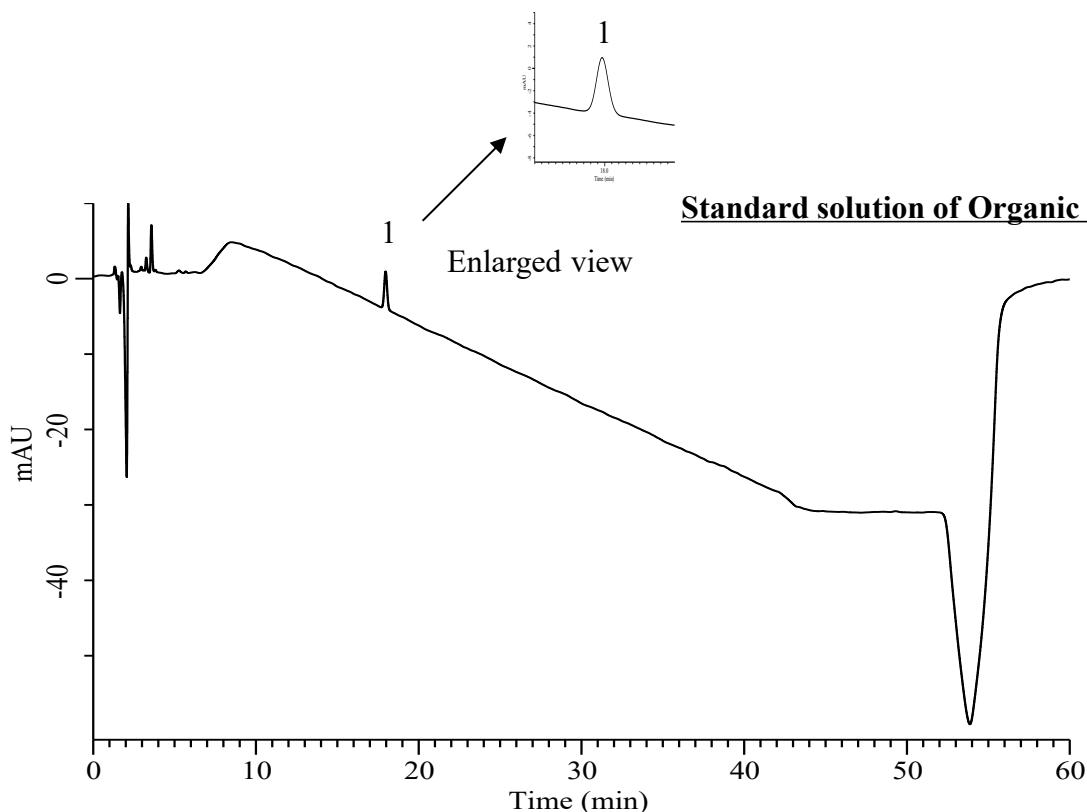


# Analysis of Fesoterodine Fumarate

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



Standard solution of Organic Impurities

**Conditions**

- System** : Chromaster HPLC system (HITACHI)
- Column** : InertSustain C8 (GL Sciences Inc.)  
(5  $\mu$  m, 250 x 4.6 mm I.D.)
- Column Cat. No.** : 5020-16028
- Eluent** : A) CH<sub>3</sub>CN/Buffer\* = 80/20 , v/v  
B) CH<sub>3</sub>CN/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

**Analyte:**

1. Fesoterodine fumarate 0.75  $\mu$  g/mL

RSD of the peak area (%) (n=6) : 0.88 ( $\leq$  5.0)

Signal-to-noise ratio : 13.2 ( $\geq$  10)

- Flow Rate** : 1.8 mL/min
- Col. Temp.** : 45  $^{\circ}$ C
- Detection** : UV 220 nm
- Injection Vol.** : 100  $\mu$  L
- Sample** : Standard

\* : 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.