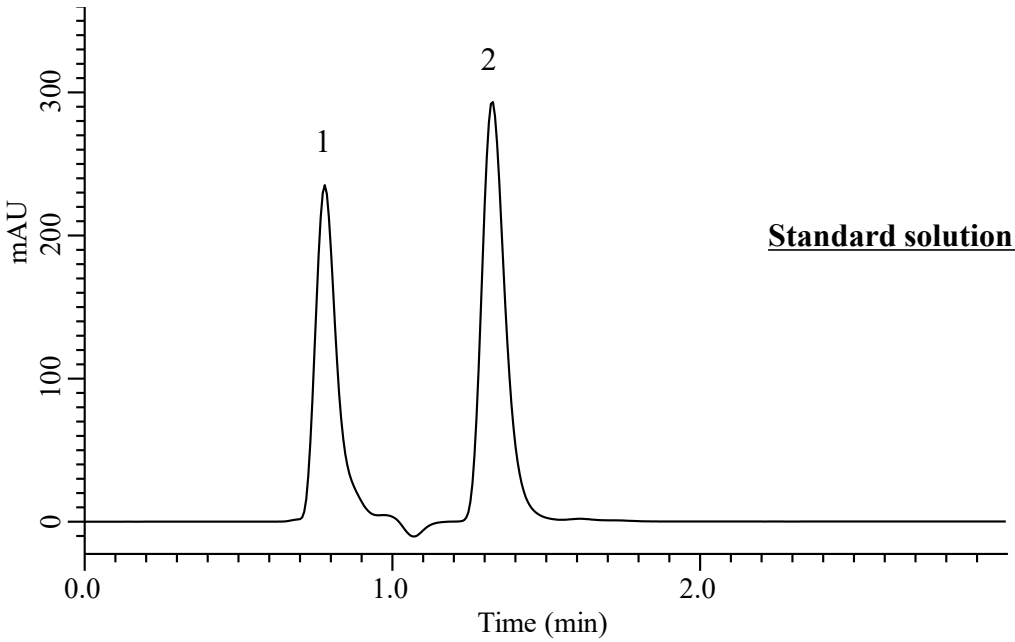
Analysis of Fesoterodine Fumarate

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



Standard solution of Assay

Conditions

System	: Chromaster HPLC system (HITACHI)
Column	: InertSustainSwift C18 (GL Sciences Inc.) (5 μm, 50 x 4.6 mm I.D.)
Column Cat. No.	: 5020-88023
Eluent	: A) CH_3CN B) Buffer* A/B = 45/55, v/v
Flow Rate	: 0.8 mL/min
Col. Temp.	: 40 ℃
Detection	: UV 220 nm (5430 DAD)
Injection Vol.	: 10 μL
Sample	: Standard

Analyte:

1. Impurity	
2. Fesoterodine fumarate	0.08 mg/mL
Tailing factor	: 1.25 (≦ 2.0)
RSD of the peak area (%)(n=6)	: 0.16 (≦ 1.0)

* : 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.