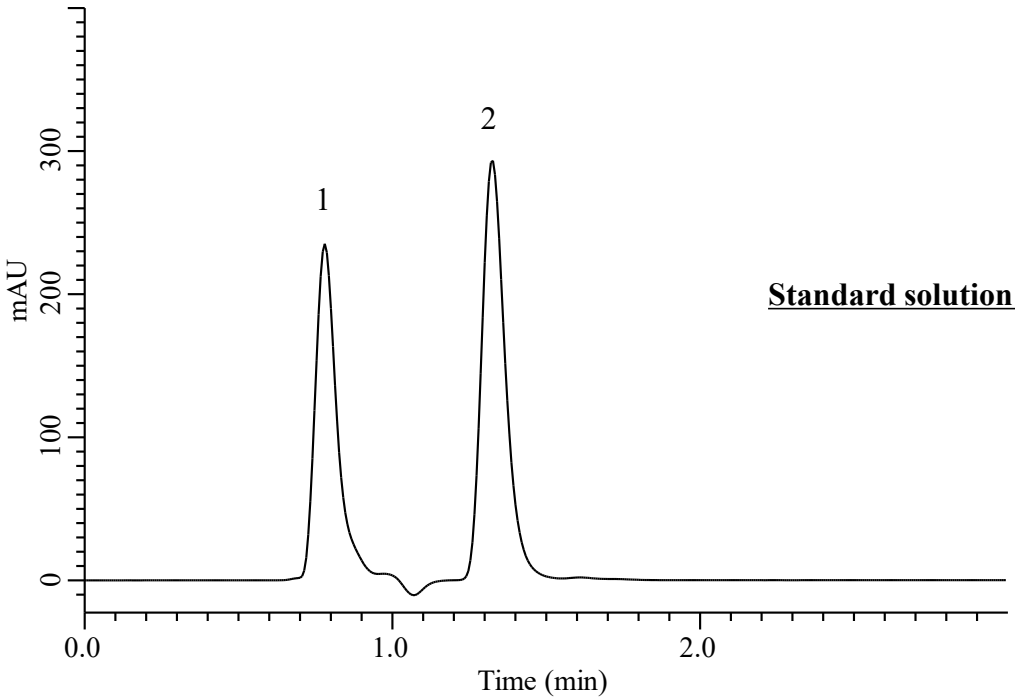
# Analysis of Fesoterodine Fumarate

**(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) $CH_3CN$<br>B) Buffer*<br>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.