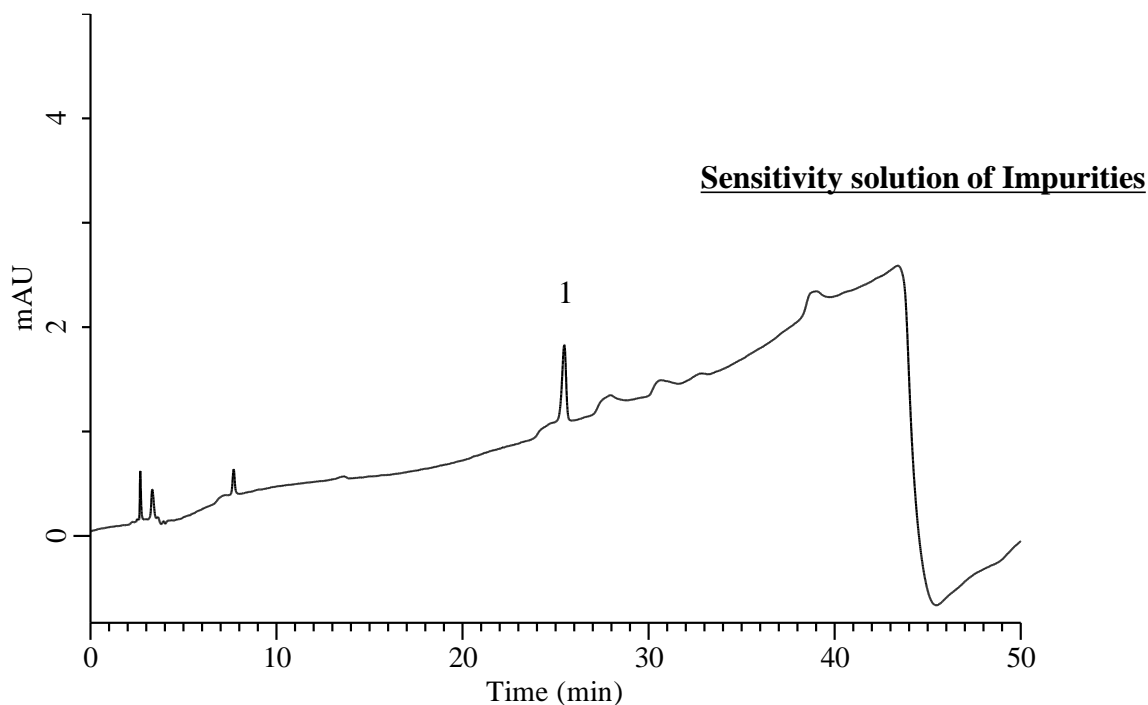


Analysis of Febuxostat

(Under the Condition of Draft for USP, Febuxostat)



Conditions

System : Chromaster HPLC system (HITACHI)
Column : InertSustain Phenyl HP (GL Sciences Inc.)
 (3 μ m, 300 x 4.6 mm I.D.)
Column Cat. No. : 5020-
Eluent : A) CH₃CN/ Buffer* = 25/75, v/v
 B) CH₃CN/ Buffer* = 75/25, v/v

Analyte:

1. Febuxostat 0.00025 mg/mL
 Signal-to-noise ratio : 88.2 (≥ 10)
 RSD of the peak area (n=6) : 0.76 (≤ 5.0)

| Time (min) | A (vol %) | B (vol %) |
|------------|-----------|-----------|
| 0.0 | 90 | 10 |
| 40.0 | 35 | 65 |
| 40.1 | 90 | 10 |
| 50.0 | 90 | 10 |

Flow Rate : 1.2 mL/min
Col. Temp. : 50 °C
Detection : UV 218 nm
Injection Vol. : 10 μ L
Sample : Standard

*Dissolve 1.36 g of potassium phosphate monobasic in 1 L of water. Adjust with 67 mL/L of phosphoric acid in water to a pH of 3.0.