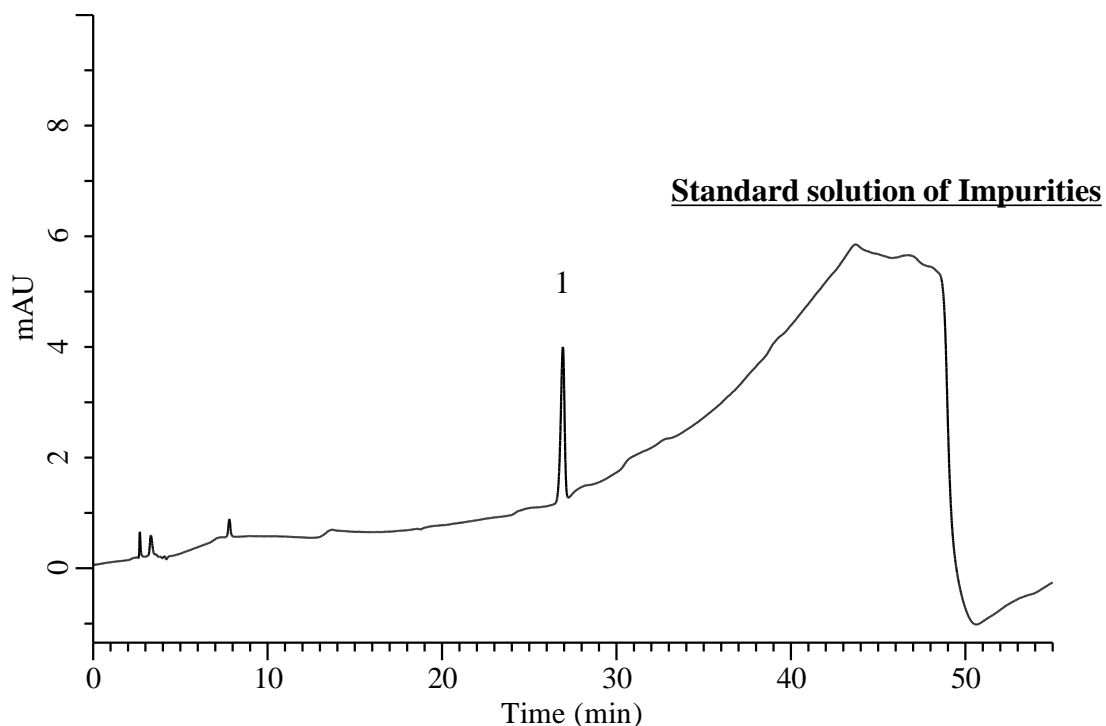


Analysis of Febuxostat

(Under the Condition of Draft for USP, Febuxostat Tablets)



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 1 μ g/mL
 RSD of the peak area (n=6) : 0.83 (\leq 5.0)
 Signal-to-noise ratio : 160.4 (\geq 10)

Time (min)	A (vol %)	B (vol %)
0.0	90	10
40.0	35	65
45.0	35	65
45.1	90	10
55.0	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 2.6.