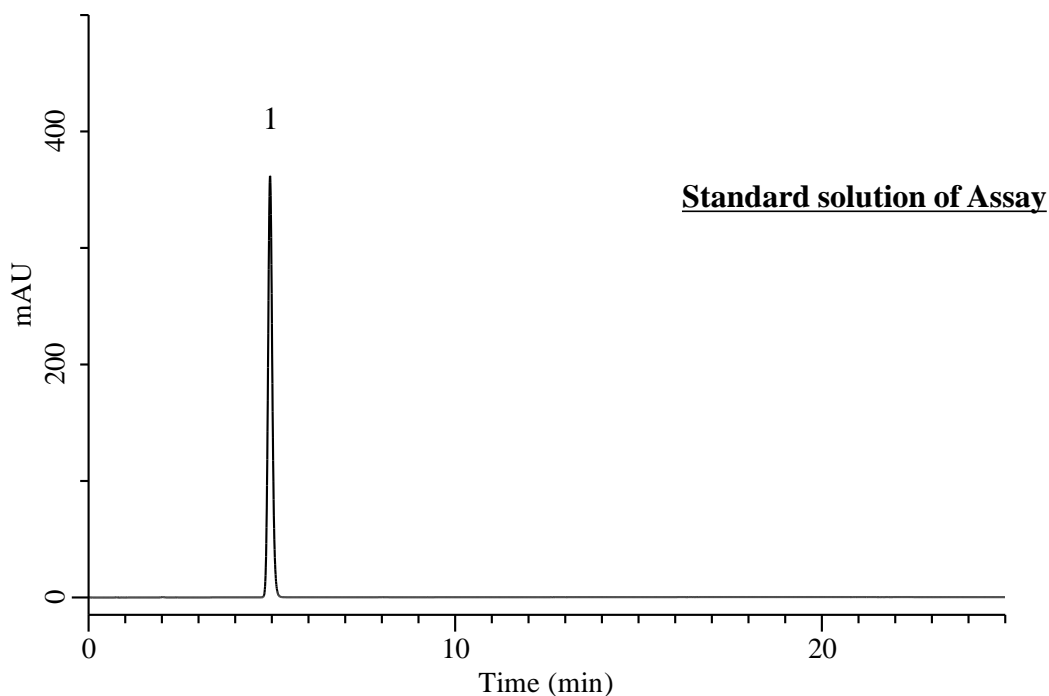


Analysis of Febuxostat

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



Conditions

System : Primaide HPLC system (HITACHI)
Column : InertSustain C18 (GL Sciences Inc.)
 (3 μ m, 100 x 4.6 mm I.D.)
Column Cat. No. : 5020-07444
Eluent : A) CH₃CN
 B) CH₃OH
 C) Buffer*
 A/B/C = 35/30/35, v/v/v
Flow Rate : 1.3 mL/min
Col. Temp. : 30 °C
Detection : UV 318 nm (1430 DAD)
Injection Vol. : 10 μ L
Sample : Standard

Analyte:

1. Febuxostat 80 μ g/mL

 Tailing factor : 1.10 (0.8 - 1.8)

 RSD of the
 peak area (%) (n=6) : 0.24 (\leq 1.0)

* Dissolve 2.76 g of sodium phosphate monobasic in 1 L of water. Add 1.0 mL of triethylamine. Adjust with phosphoric acid to a pH of 2.5.