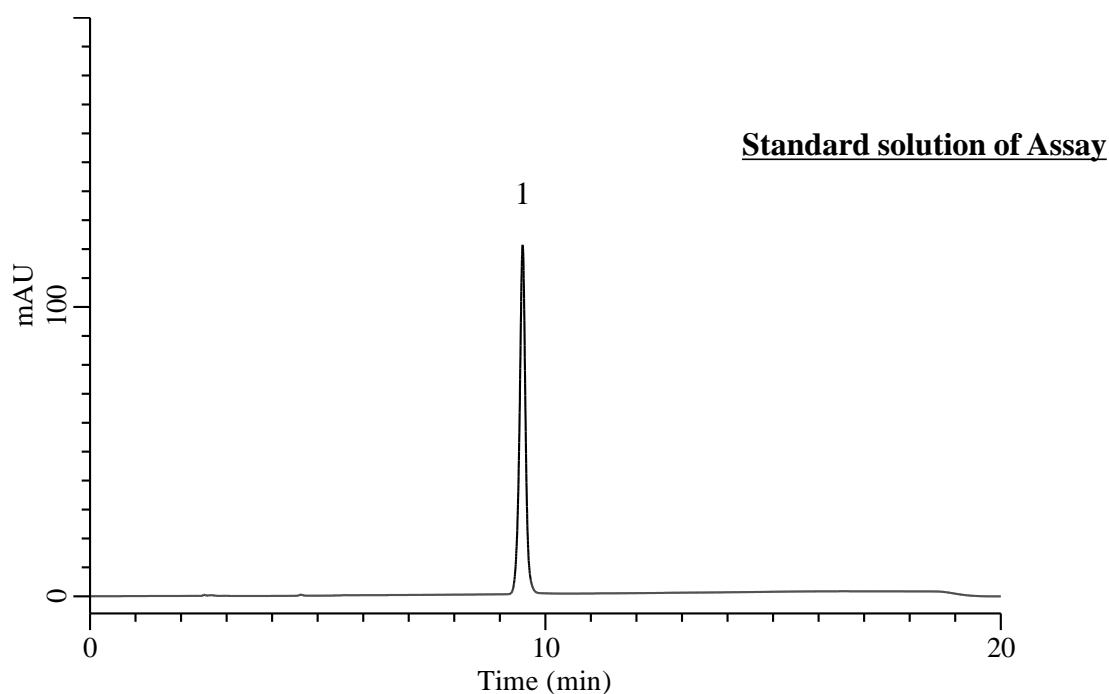


# Analysis of Febuxostat

(Under the Condition of Draft for USP, Febuxostat)



### Conditions

**System** : Chromaster HPLC system (HITACHI)  
**Column** : InertSustain Phenyl HP (GL Sciences Inc.)  
 (3  $\mu$  m, 300 x 4.6 mm I.D.)  
**Column Cat. No.** : 5020-  
**Eluent** : A) CH<sub>3</sub>CN/ Buffer\* = 25/75, v/v  
 B) CH<sub>3</sub>CN/ Buffer\* = 75/25, v/v

### Analyte:

1. Febuxostat 0.025 mg/mL  
 Tailing factor : 0.98 (0.8 - 1.8)  
 RSD of the peak area (%) (n=6) : 0.08 ( $\leq$  0.73)

Time (min)	A (vol %)	B (vol %)
0.0	55	45
12.0	35	65
15.0	35	65
15.1	55	45
20.0	55	45

**Flow Rate** : 1.2 mL/min  
**Col. Temp.** : 50 °C  
**Detection** : UV 218 nm  
**Injection Vol.** : 10  $\mu$  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.