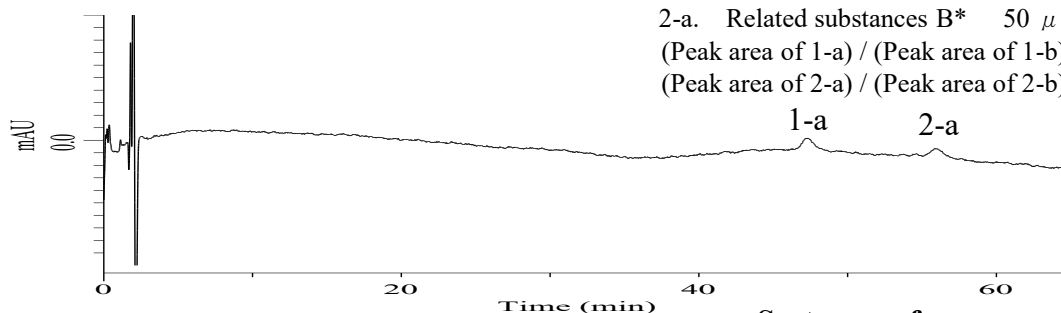


## Analysis of Febuxostat

(Under the Condition of the Japanese Pharmacopoeia 18<sup>th</sup> Supplement II, Febuxostat, Related substances (ii))

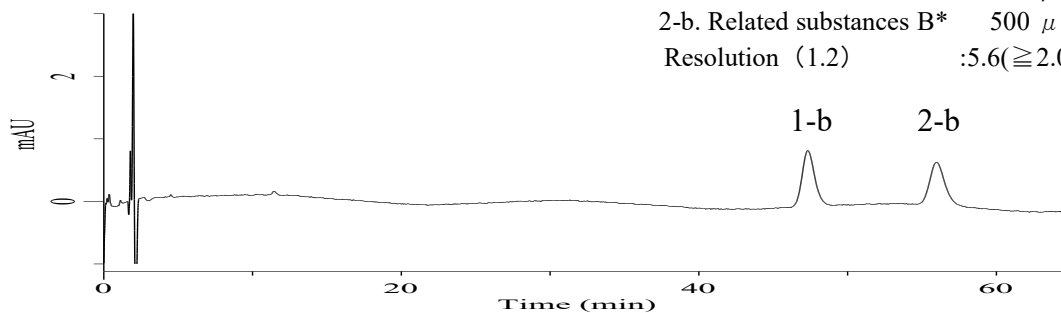
### Test for required detectability

1-a. Febuxostat 50  $\mu$  g/L  
 2-a. Related substances B\* 50  $\mu$  g/L  
 (Peak area of 1-a) / (Peak area of 1-b) :  $(7 \leq) 7.34 (\leq 13)$   
 (Peak area of 2-a) / (Peak area of 2-b) :  $(7 \leq) 7.11 (\leq 13)$



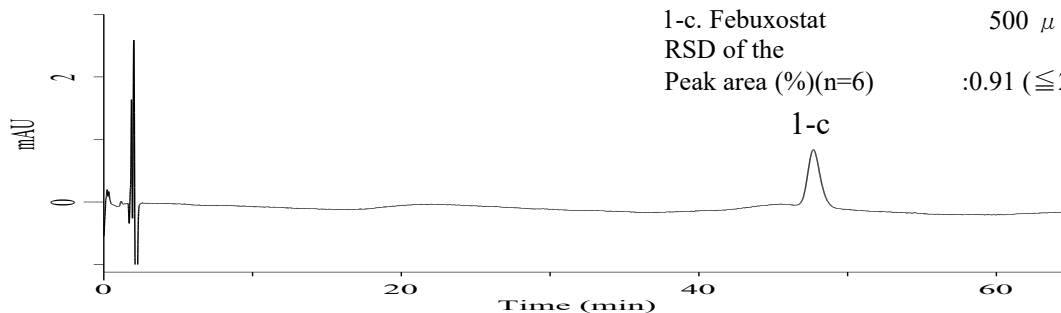
### System performance

1-b. Febuxostat 500  $\mu$  g/L  
 2-b. Related substances B\* 500  $\mu$  g/L  
 Resolution (1.2) :  $5.6 (\geq 2.0)$



### System repeatability

1-c. Febuxostat 500  $\mu$  g/L  
 RSD of the  
 Peak area (%) (n=6) :  $0.91 (\leq 2.0)$



### Conditions

**System** : Chromaster HPLC system (HITACHI)  
**Column** : InertSustain C30 (GL Sciences Inc.)  
 (HP 3  $\mu$  m, 150 x 4.6 mm I.D.)  
**Column Cat. No.** : 5020-17184  
**Eluent** : A) 0.05% CF<sub>3</sub>COOH in H<sub>2</sub>O  
 B) 0.05% CF<sub>3</sub>COOH in CH<sub>3</sub>CN  
 A/B = 55/45, v/v  
**Flow Rate** : 1.19 mL/min  
**Col. Temp.** : 15 °C  
**Detection** : UV 317 nm  
**Injection Vol.** : 20  $\mu$  L  
**Sample** : Standard

### Analyte:

1. Febuxostat  
 2. Related substances B\*

\*2-(4-Butoxy-3-cyanophenyl)-4-methyl-1,3-thiazole-5-carboxylic acid