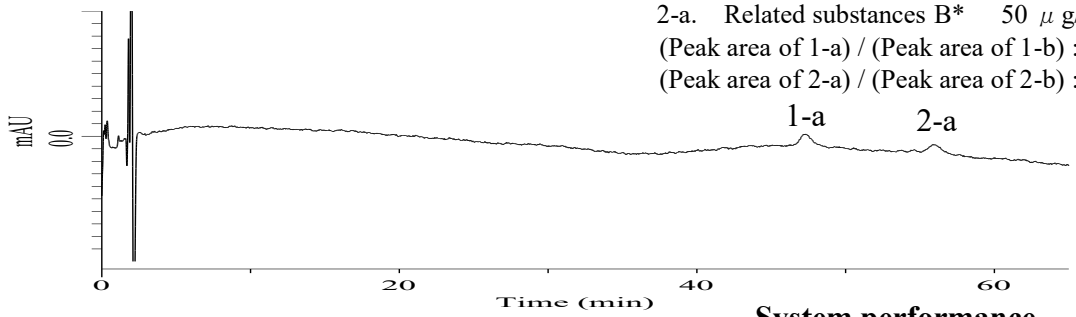
Analysis of Febuxostat

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

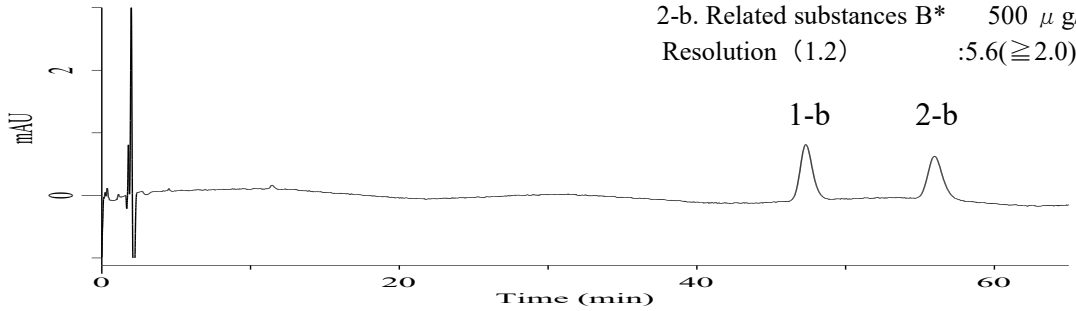
Test for required detectability

1-a. Febuxostat 50 μg/L
2-a. Related substances B* 50 μg/L
(Peak area of 1-a) / (Peak area of 1-b) : (7≦)7.34(≦13)
(Peak area of 2-a) / (Peak area of 2-b) : (7≦)7.11(≦13)



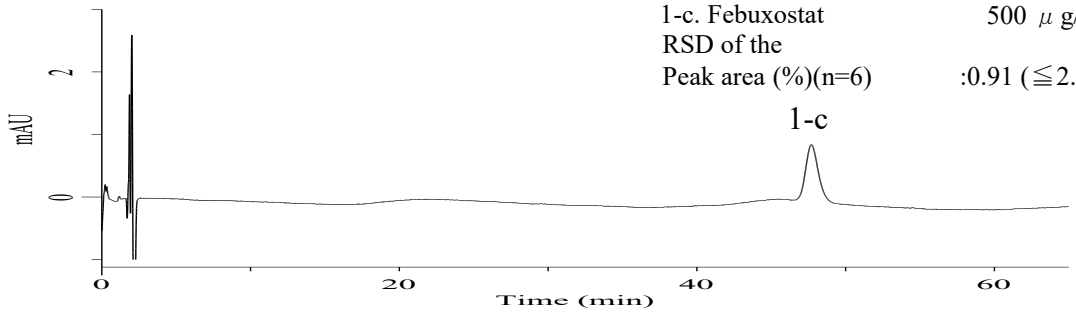
System performance

1-b. Febuxostat 500 μg/L
2-b. Related substances B* 500 μg/L
Resolution (1.2) :5.6(≧2.0)



System repeatability

1-c. Febuxostat 500 μg/L
RSD of the
Peak area (%)(n=6) :0.91 (≦2.0)



Conditions

System : Chromaster HPLC system (HITACHI)
Column : InertSustain C30 (GL Sciences Inc.)
(HP 3 μm, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020-17184
Eluent : A) 0.05% CF_3COOH in H_2O
B) 0.05% CF_3COOH in CH_3CN
A/B =55/45, v/v
Flow Rate : 1.19 mL/min
Col. Temp. : 15 ℃
Detection : UV 317 nm
Injection Vol. : 20 μL
Sample : Standard

Analyte:
1. Febuxostat
2. Related substances B*

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