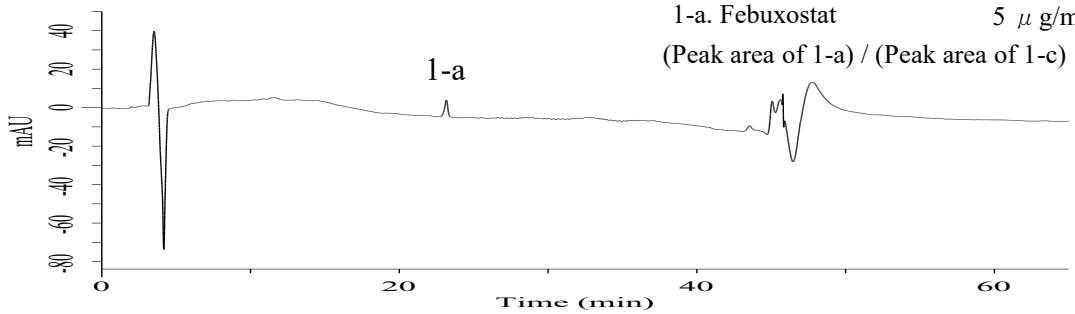
Analysis of Febuxostat

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

Test for required detectability

1-a. Febuxostat 5 μg/mL

(Peak area of 1-a) / (Peak area of 1-c) : (7≦) 8.68 (≦13)

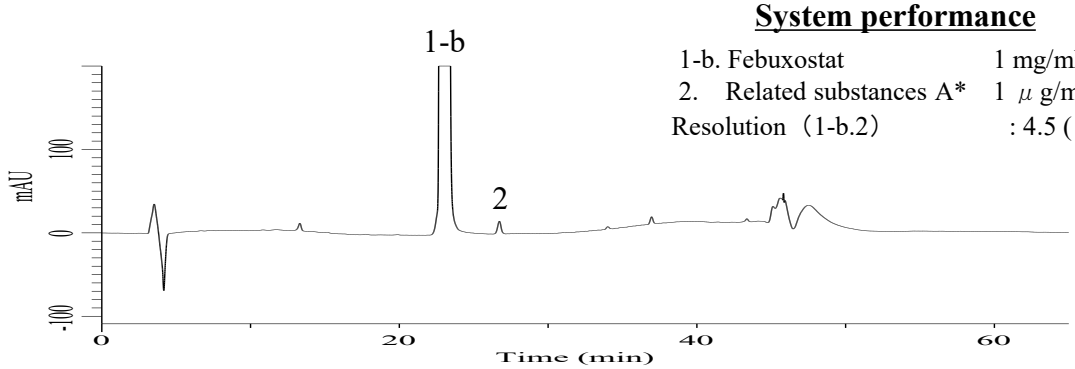


System performance

1-b. Febuxostat 1 mg/mL

2. Related substances A* 1 μg/mL

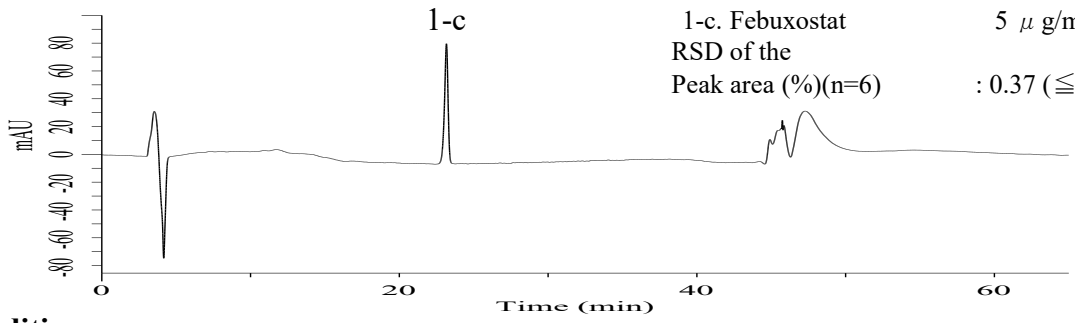
Resolution (1-b.2) : 4.5 (≧2.0)



System repeatability

1-c. Febuxostat 5 μg/mL

RSD of the Peak area (%)(n=6) : 0.37 (≦2.0)



Conditions

System : Chromaster HPLC system (HITACHI)

Column : InertSustain AQ-C18 (GL Sciences Inc.) (5 μm, 250 x 4.6 mm I.D.)

Column Cat. No. : 5020-89731

Eluent : A) 0.02% CH_3COOH in H_2O
B) 0.02% CH_3COOH in CH_3CN

Time(min)	A(vol%)	B(vol%)
0.0	60	40
40.0	0	100

Flow Rate : 0.70 mL/min

Col. Temp. : 40 °C

Detection : UV 217 nm

Injection Vol. : 40 μL

Sample : Standard

Analyte:

1. Febuxostat
2. Related substances A*

* 2-[3-Ethoxycarbonyl-4-(2-methylpropoxy)phenyl]-4-methyl-1,3-thiazole-5-carboxylic acid