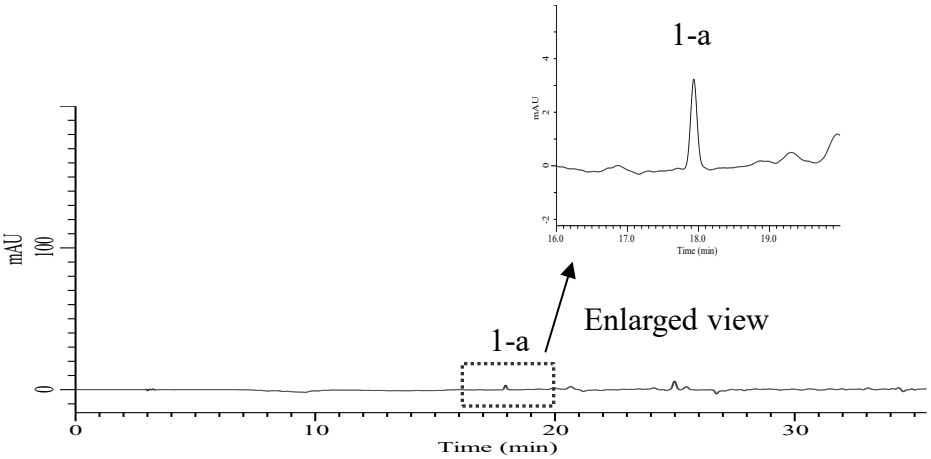
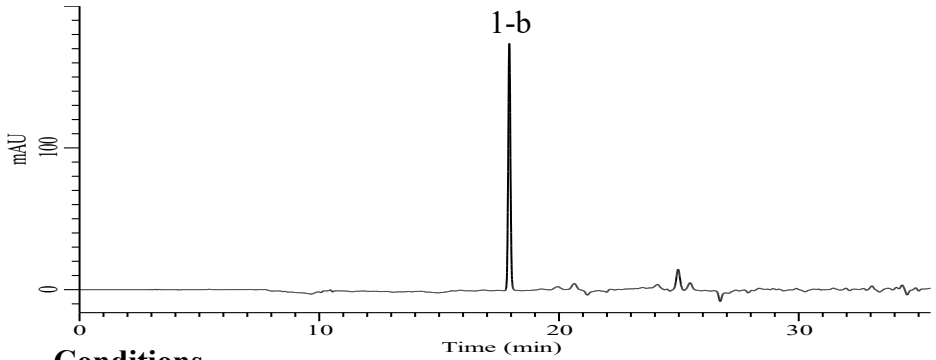
Analysis of Cefalexin

(Under the Condition of the Japanese Pharmacopoeia 18th, Cefalexin, Purity(3) Related substances)

Test for required detectability



Standard solution



These chromatograms were corrected with the results of solution C injection. for the chage of base-line due to the potassium dihydrogenphosphate solution.

Conditions

System : Chromaster PLUS (HITACHI)
Column : InertSustainSwift C18 (GL Sciences Inc.) (5 µm, 250 x 4.6 mm I.D.)
Column Cat. No. : 5020-88027
Eluent : A) Solution A
B) Solution B

Time (min)	A (vol %)	B (vol %)
0	0	100
1.0	0	100
34.5	100	0
35.5	100	0

Flow Rate : 1.0 mL/min
Col. Temp. : 25 °C
Detection : UV 254 nm (Chromaster 5430 DAD)
Injection Vol. : 20 µL
Sample : Standard in Solution C

Analyte:

1-a. Cefalexin	1.0 mg/mL
1-b. Cefalexin	50.0 mg/mL

Test for required detectability (1-a)
: (1.8 ≦) 1.93 (≦ 2.2)

Tailing factor (1-b) : (0.8 ≦) 1.07 (≦ 1.3)

Number of theoretical plates (1-b)
: 171852 (≧ 150000)

RSD of
the retention time of 1-b (%)(n=3) : 0.02 (≦ 2.0)
the peak area of 1-b (%)(n=3) : 0.25 (≦ 2.0)

Solution A : Dissolve 1.0 g of sodium 1-pentanesulfonate in 300 mL of water, add 15 mL of triethylamine, and adjust to pH 2.5 with phosphoric acid. To this solution add 350 mL of acetonitrile and 350 mL of methanol.

Solution B : Dissolve 1.0 g of sodium 1-pentanesulfonate in 1000 mL of water, add 15 mL of triethylamine, and adjust to pH 2.5 with phosphoric acid.

Solution C : Dissolve 9g of potassium dihydrogenphosphate in water to make 500mL.