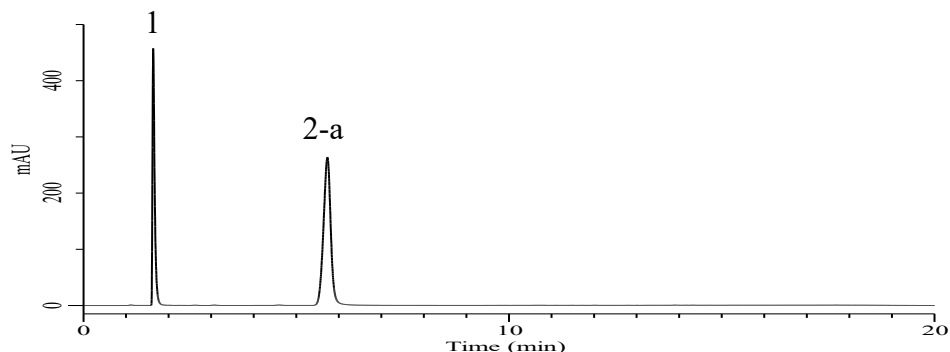
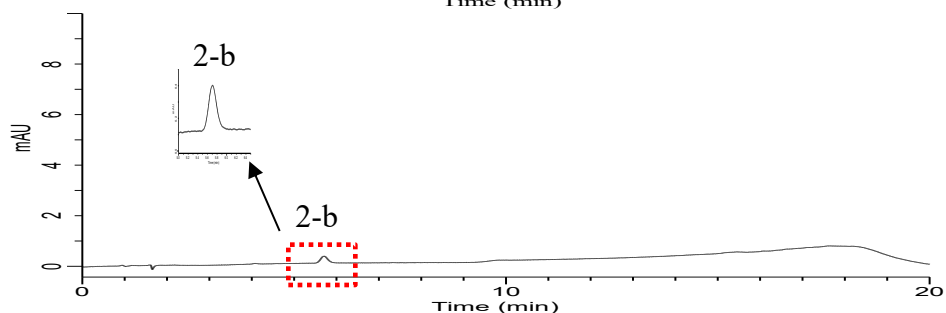


Analysis of Ampicillin

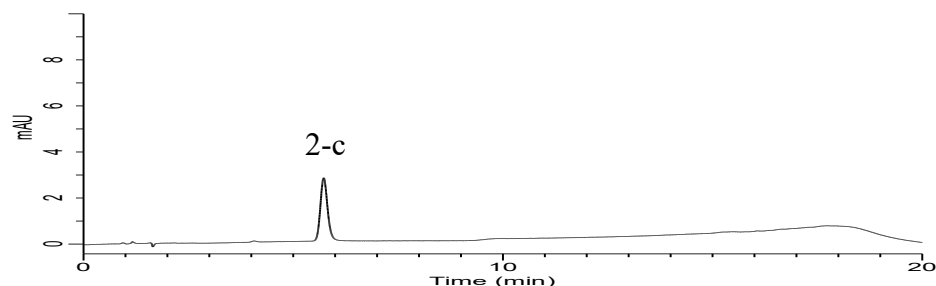
(Under the Condition of USP PF52(2), Ampicillin, Organic Impurities, Procedure 1)



System Suitability solution



Sensitivity solution



Standard solution

Conditions

System : Primaide (HITACHI)
Column : Inertsil ODS-3 (GL Sciences Inc.)
 (5 μm, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020-01731
Eluent : A) CH₃CN/Solution* = 30/70, v/v
 B) CH₃CN/Solution* = 8/92, v/v

Analyte:

1. Amoxicillin 0.1 mg/mL
 2-a. Ampicillin 0.5 mg/mL
 2-b. Ampicillin 0.5 μg/mL
 2-c. Ampicillin 5.0 μg/mL

Time (min)	A (vol %)	B (vol %)
0.0	0	100
6.0	0	100
15.0	100	0
16.0	100	0
18.0	0	100
20.0	0	100

Resolution (1, 2-a) : 20.6 (≥10)
 Tailing Factor (2-a) : 0.98 (≤ 1.4)
 Signal-to-noise ratio (2-b) : 50.8 (≥ 3)
 RSD of the peak (2-c) area (%) (n=6) : 0.87 (≤ 5.0)

Flow Rate : 1.5 mL/min
Col. Temp. : 40 °C
Detection : UV 230 nm (Primaide 1410 UV)
Injection Vol. : 20 μL
Sample : Standard

Relative Retention Times
 Amoxicillin : 0.28
 Ampicillin : 1.0

*: 6.54 g/L of monobasic potassium phosphate and 0.34 g/L of dibasic potassium phosphate. (pH 5.5)