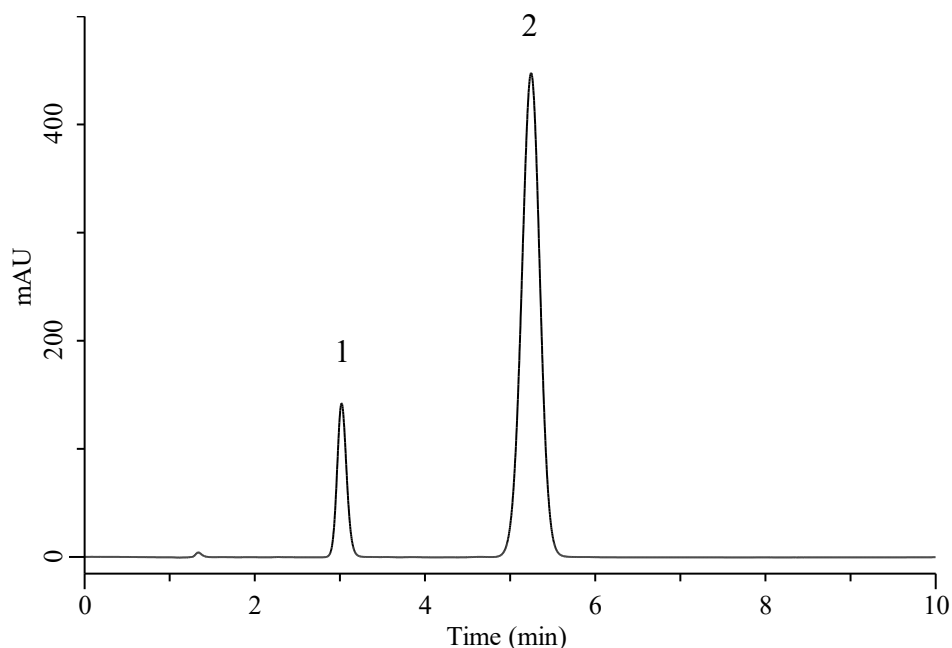


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Analysis of Amoxicillin and Clavulanate potassium

Data No. LB859-7111



Conditions

System : Primaide HPLC system (HITACHI)
Column : Inertsil ODS-3 (GL Sciences Inc.)
(10 μ m, 300 x 3.9 mm I.D.)
Column Cat. No. : 5020-87016
Eluent : CH₃OH/Buffer* = 1/19, v/v
Flow Rate : 2.0 mL/min
Col. Temp. : 40 °C
Detection : UV 220 nm
Injection Vol. : 20 μ L
Sample : Standard

Analyte:

1. Clavulanate potassium —
2. Amoxicillin 500 μ g/mL

Relative retention times
Clavulanate potassium : 3.02/5.24 (0.57)
Amoxicillin : 5.24/5.24 (1.0)

Resolution : 7.16 (\geq 3.5)

Tailing factor (1) : 1.08 (\leq 1.5)

Tailing factor (2) : 0.97 (\leq 1.5)

RSD of the
peak area of 1 (%)(n=6) : 0.07 (\leq 2.0)
peak area of 2 (%)(n=6) : 0.06 (\leq 2.0)

*: 7.8 g of monobasic sodium phosphate in 900 mL of water. Adjust with phosphoric acid to a pH of 4.4 \pm 0.1, and dilute with water to 1000 mL.