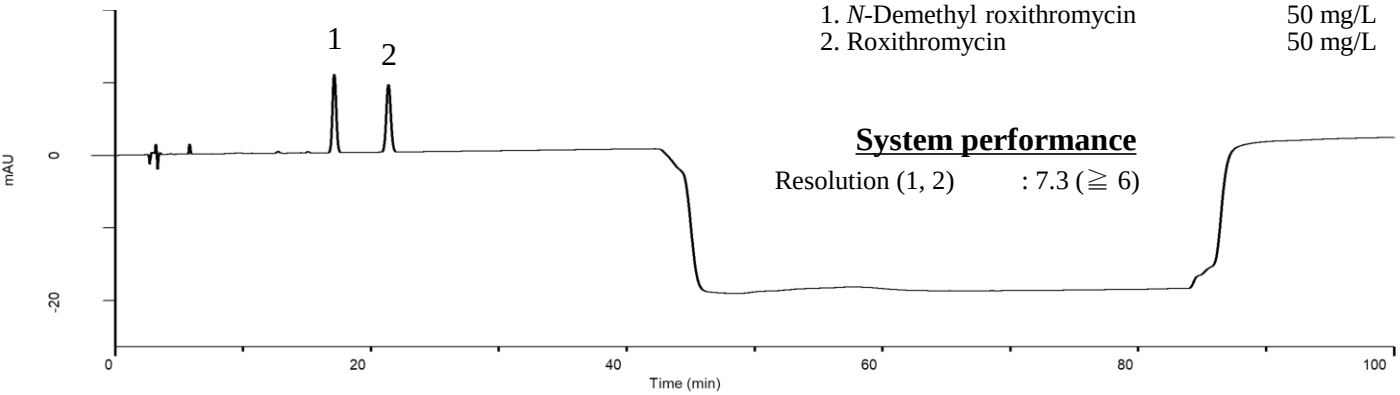
Analysis of Roxithromycin

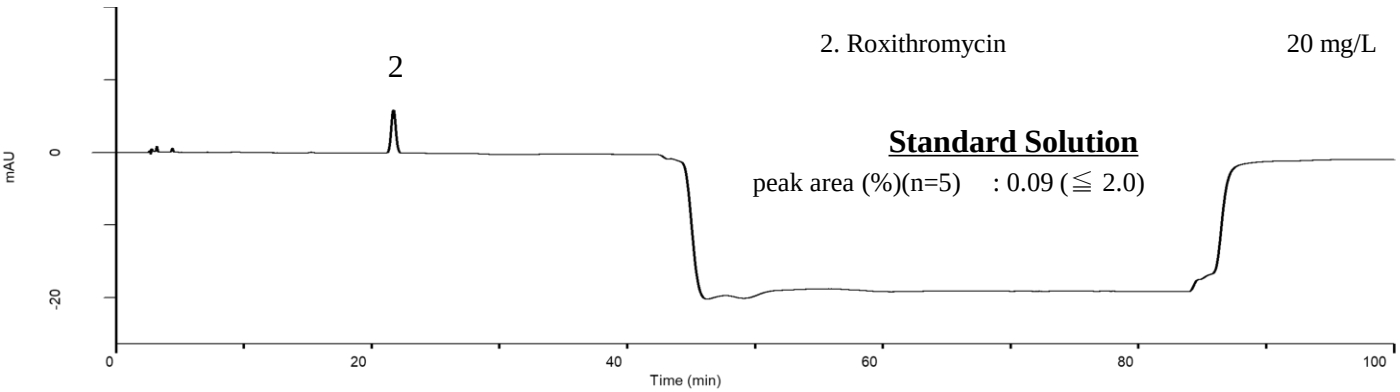
(Under the Condition of the Japanese Pharmacopoeia 16th edition)



1. *N*-Demethyl roxithromycin 50 mg/L
2. Roxithromycin 50 mg/L

System performance

Resolution (1, 2) : 7.3 (≧ 6)



2. Roxithromycin 20 mg/L

Standard Solution

peak area (%)(n=5) : 0.09 (≦ 2.0)

Conditions

System : GL7700 HPLC system
Column : InertSustainSwift C18 (5 μm, 250 x 4.6 mm I.D.)
Column Cat. No. : 5020-88027
Eluent : A) Buffer*
B) CH_3CN/H_2O = 70/30, v/v

Time (min)	A (vol%)	B (vol%)
0.0	100	0
38.0	100	0
39.0	90	10
80.0	90	10
80.1	100	0
100.0	100	0

Flow Rate : 0.92 mL/min
Col. Temp. : 25 ℃
Detection : UV 205 nm (UV7750 UV Detector)
Injection Vol. : 20 μL
Sample : Standard

*Dissolve 34 g of ammonium dihydrogenphosphate in 710 mL of water. Adjust pH 5.3 by 2 mol/L sodium hydroxide test solution. Add 315 mL of acetonitrile.

Analyte:

1. *N*-Demethyl roxithromycin
2. Roxithromycin

【NOTE】

1) The retention time will be shifted easily under this conditions.
2) Salting-out will be occurred due to high concentration buffer.