

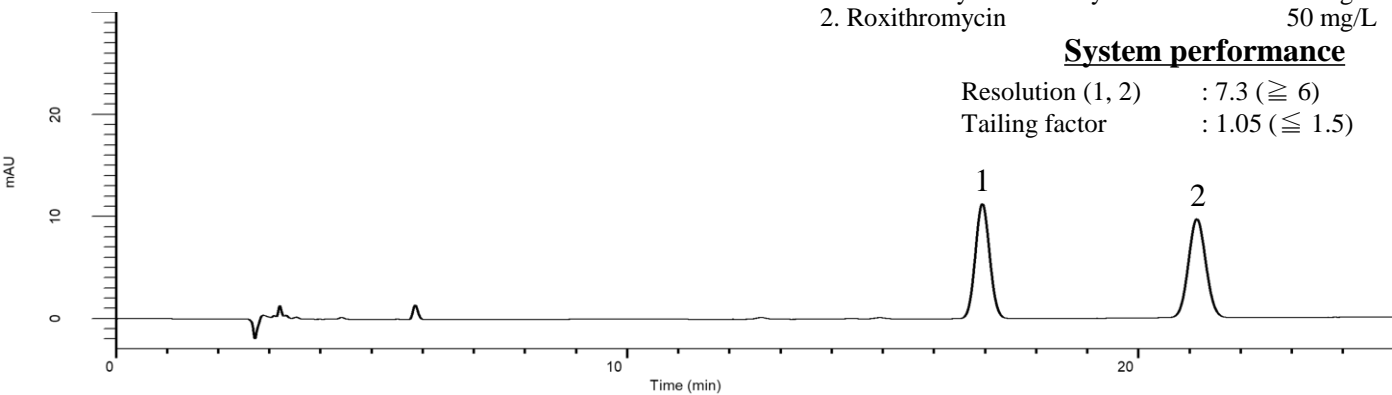
Analysis of Roxithromycin

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

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

System performance

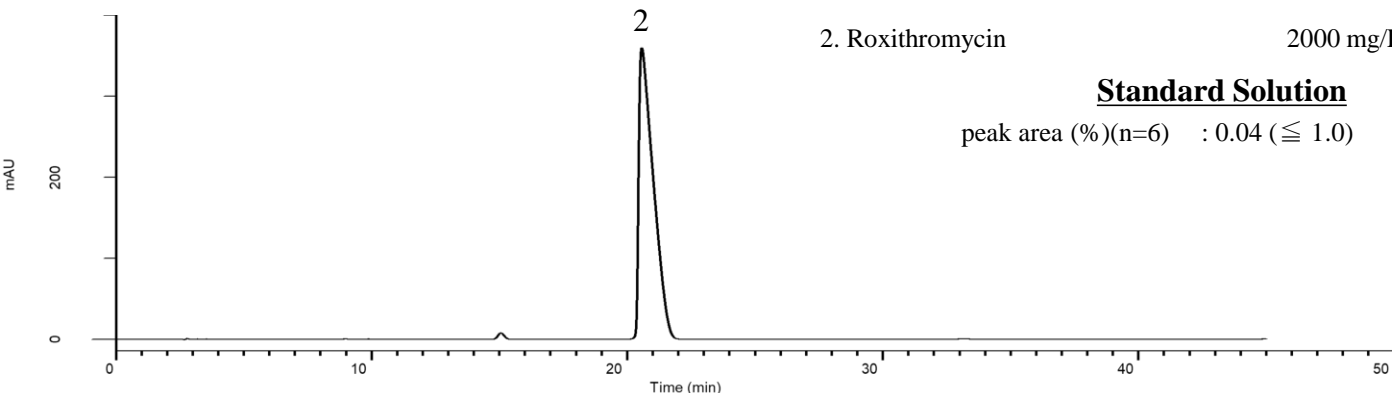
Resolution (1, 2) : 7.3 (≥ 6)
 Tailing factor : 1.05 (≤ 1.5)



2. Roxithromycin 2000 mg/L

Standard Solution

peak area (%) (n=6) : 0.04 (≤ 1.0)



Conditions

System : GL7700 HPLC system
Column : InertSustainSwift C18
 (5 μ m, 250 x 4.6 mm I.D.)
Column Cat. No. : 5020-88027
Eluent : A) Buffer*
 B) CH₃CN/H₂O = 70/30, v/v
Flow Rate : 0.92 mL/min
Col. Temp. : 25 °C
Detection : UV 205 nm (UV7750 UV Detector)
Injection Vol. : 20 μ L
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.