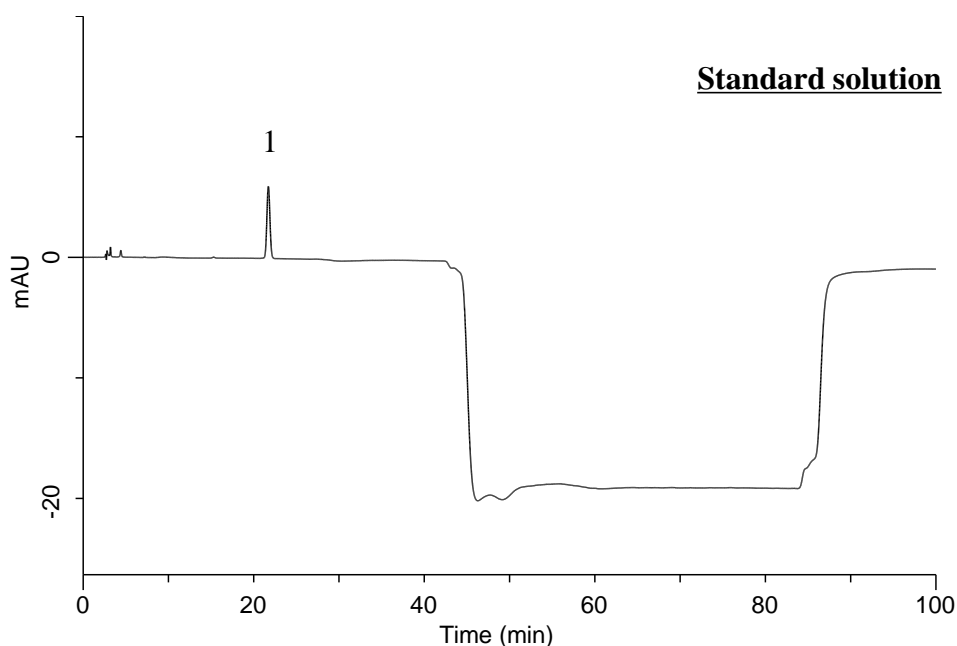


Analysis of Roxithromycin

(Under the Condition of the Japanese Pharmacopoeia)



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

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 °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. Roxithromycin 20 mg/L

Theoretical plates : 17,431 (\geq 9,000)

Tailing factor : 1.05 (\leq 1.5)

RSD of the
 peak area (%) (n=5) : 0.09 (\leq 2.0)

【NOTE】

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