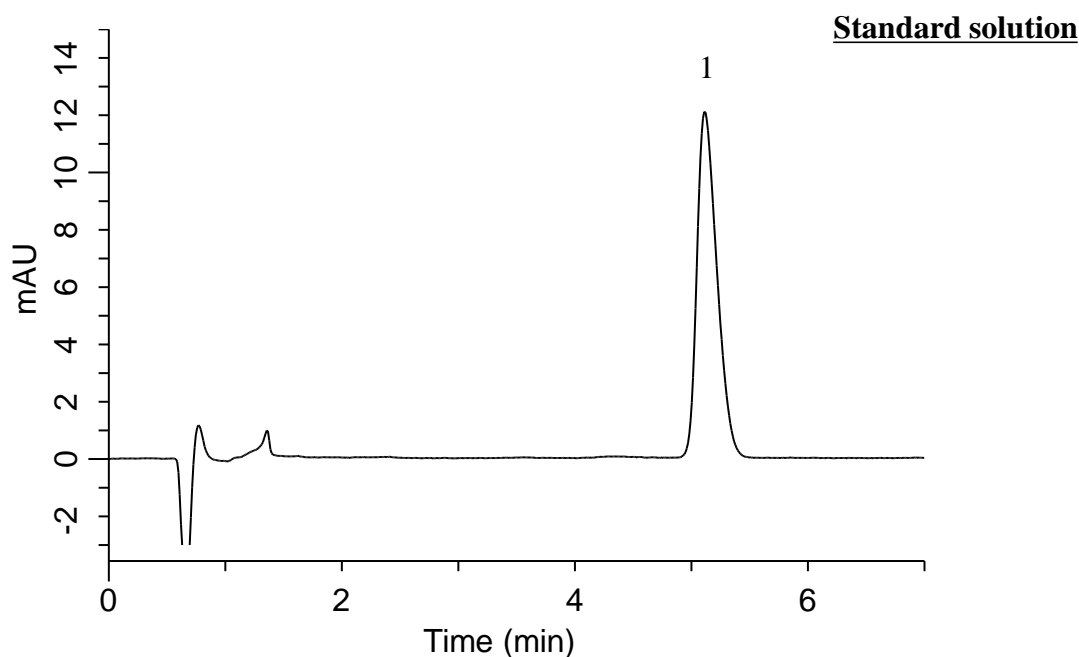


Analysis of Roxithromycin

(Under the Condition of the Japanese Pharmacopoeia, Roxithromycin Tablets)



Conditions

System : GL7700 HPLC system
Column : InertSustain C18
 (5 μ m, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020-07345
Eluent : A) CH₃CN
 B) Buffer*
 A/B = 31/69, v/v
Flow Rate : 1.75 mL/min
Col. Temp. : 25 °C
Detection : UV 230 nm (UV7750 UV Detector)
Injection Vol. : 50 μ L
Sample : Standard

Analyte:

1. Roxithromycin 165 mg/L

Theoretical plates : 4,228 (\geq 2,300)
 Tailing factor : 1.40 (\leq 2.0)
 RSD of the
 peak area (%) (n=6) : 0.16 (\leq 1.0)

*Dissolve 49.1 g of ammonium dihydrogenphosphate to 1,000 mL of water.
 Adjust pH 5.3 by 2 mol/L sodium hydroxide test solution.

【NOTE】

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