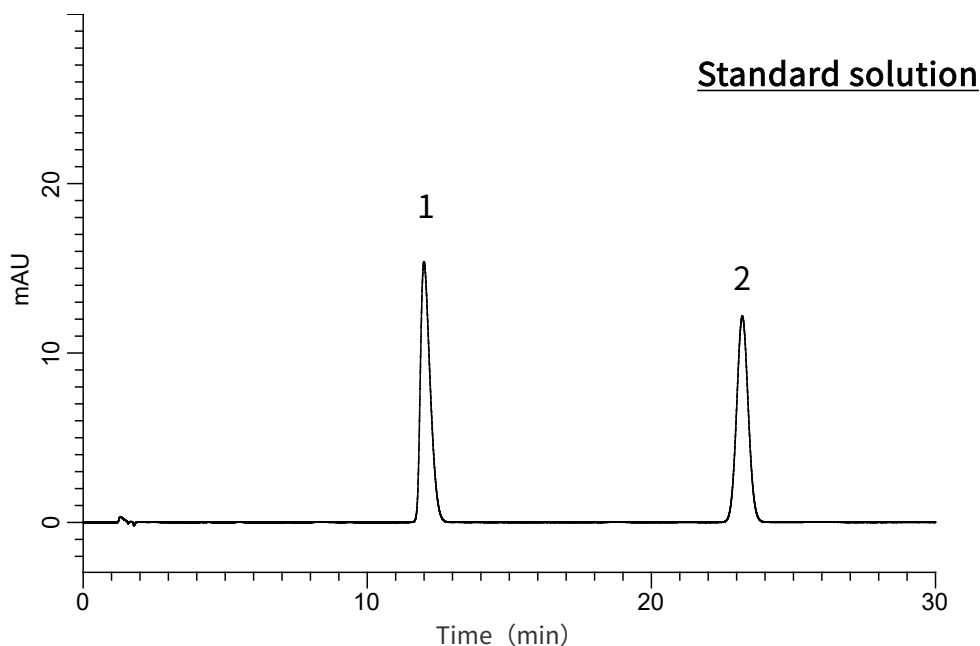


Analysis of Roxithromycin

(Under the Condition of the Japanese Pharmacopoeia)

Data No. LB330-0919



Conditions

System : GL7700 HPLC system
Column : InertSustain C18
 (5 μ m, 250 x 4.6 mm I.D.)
Column Cat. No. : 5020-07346
Eluent : A) CH₃CN
 B) Buffer*
 A/B = 31/69, v/v
Flow Rate : 1.4 mL/min
Col. Temp. : 25 °C
Detection : UV 230 nm (UV7750 UV Detector)
Injection Vol. : 10 μ L
Sample : Standard

*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.

Analyte:

1. Roxithromycin 1520 mg/L
 2. *p*-Hydroxybenzoic acid *iso*-propyl ester 50 mg/L

Resolution (1, 2) : 16.2 (≥ 10)

RSD of the peak
 area ratio of

1 to 2 (%) (n=6) : 0.04 (≤ 1.0)

【NOTE】

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