

# InertSearch™ for LC

Inertsil® Applications

## Analysis of Roxithromycin

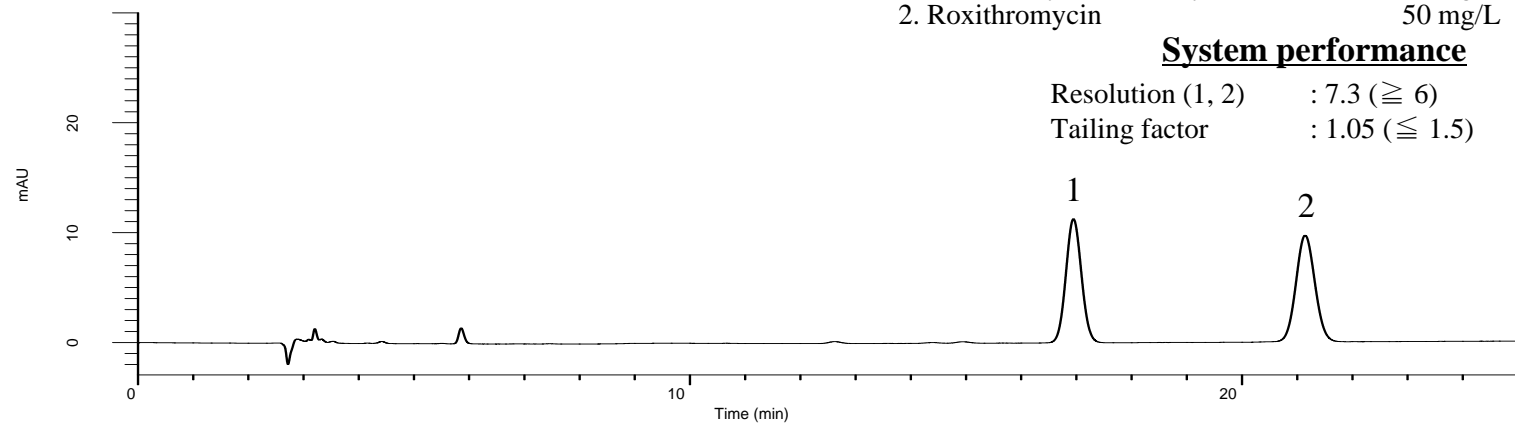
(Under the Condition of the Japanese Pharmacopoeia 16<sup>th</sup> edition supplement II)

Data No. LB328-0919

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

### System performance

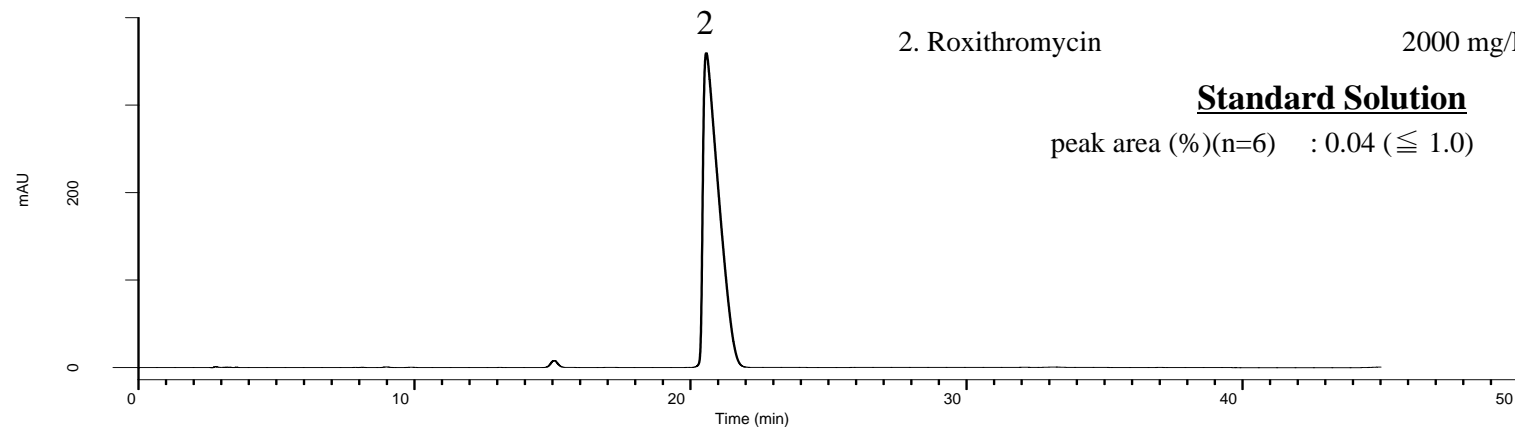
Resolution (1, 2) : 7.3 ( $\geq 6$ )  
Tailing factor : 1.05 ( $\leq 1.5$ )



2. Roxithromycin 2000 mg/L

### Standard Solution

peak area (%) (n=6) : 0.04 ( $\leq 1.0$ )



### Conditions

**System** : GL7700 HPLC system  
**Column** : InertSustainSwift C18  
(5  $\mu$  m, 250 x 4.6 mm I.D.)  
**Column Cat. No.** : 5020-88027  
**Eluent** : A) Buffer\*  
B) CH<sub>3</sub>CN/H<sub>2</sub>O = 70/30, v/v  
**Flow Rate** : 0.92 mL/min  
**Col. Temp.** : 25 °C  
**Detection** : UV 205 nm (UV7750 UV Detector)  
**Injection Vol.** : 20  $\mu$  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.