

### Analysis of Pazufloxacin mesilate

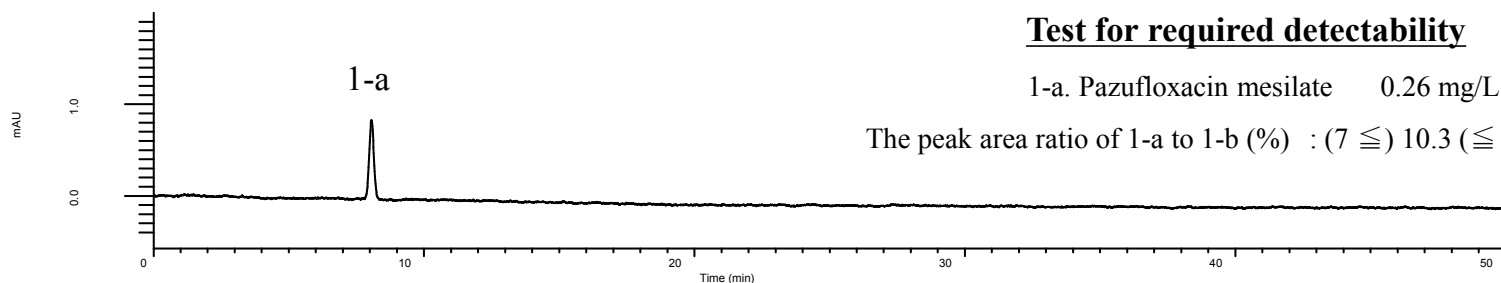
(Under the Condition of the draft for the Japanese Pharmacopoeia)

Data No. LB444-0894

#### Test for required detectability

1-a. Pazufloxacin mesilate 0.26 mg/L

The peak area ratio of 1-a to 1-b (%) :  $(7 \leq) 10.3 (\leq 13)$



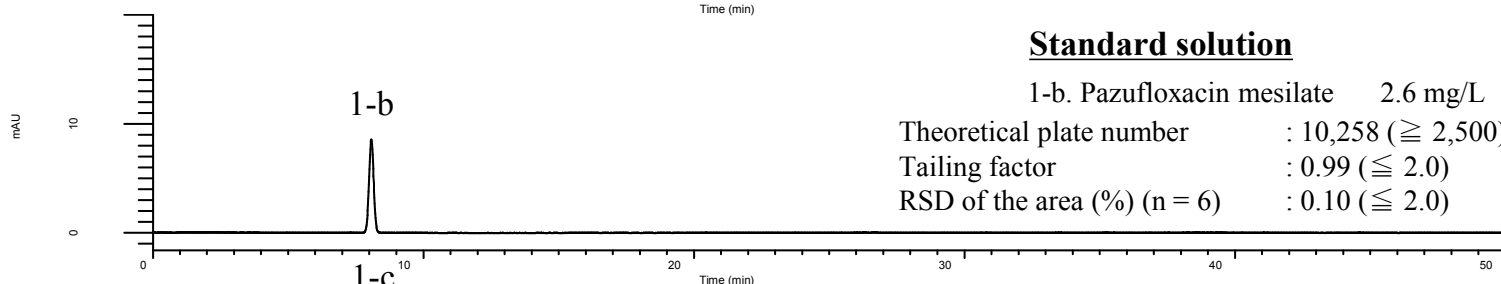
#### Standard solution

1-b. Pazufloxacin mesilate 2.6 mg/L

Theoretical plate number :  $10,258 (\geq 2,500)$

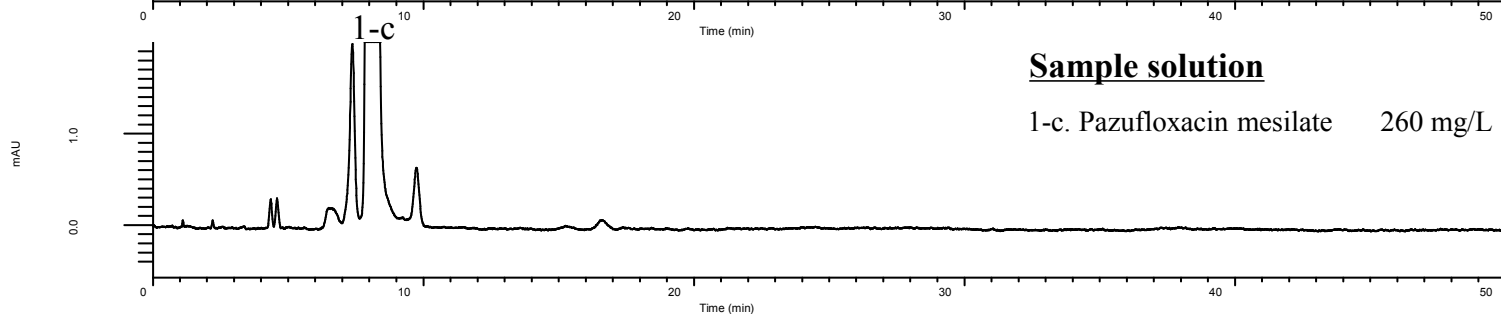
Tailing factor :  $0.99 (\leq 2.0)$

RSD of the area (%) (n = 6) :  $0.10 (\leq 2.0)$



#### Sample solution

1-c. Pazufloxacin mesilate 260 mg/L



#### Conditions

**System** : GL7700 HPLC system  
**Column** : Inertsil ODS-2  
(5  $\mu$  m, 150 x 4.6 mm I.D.)  
**Column Cat. No.** : 5020-01124  
**Eluent** : Buffer\*  
**Flow Rate** : 1.57 mL/min  
**Col. Temp.** : 40 °C  
**Detection** : UV 254 nm (PD7752 PDA Detector)  
**Injection Vol.** : 20  $\mu$  L  
**Sample** : Standard

#### Analyte:

1. Pazufloxacin mesilate

\*Dissolve 1.08 g of sodium 1-octanesulfonate in 1000 mL of a mixture of diluted phosphoric acid (1 in 1000) and acetonitrile (39:11).