

Analysis of Pazufloxacin mesilate

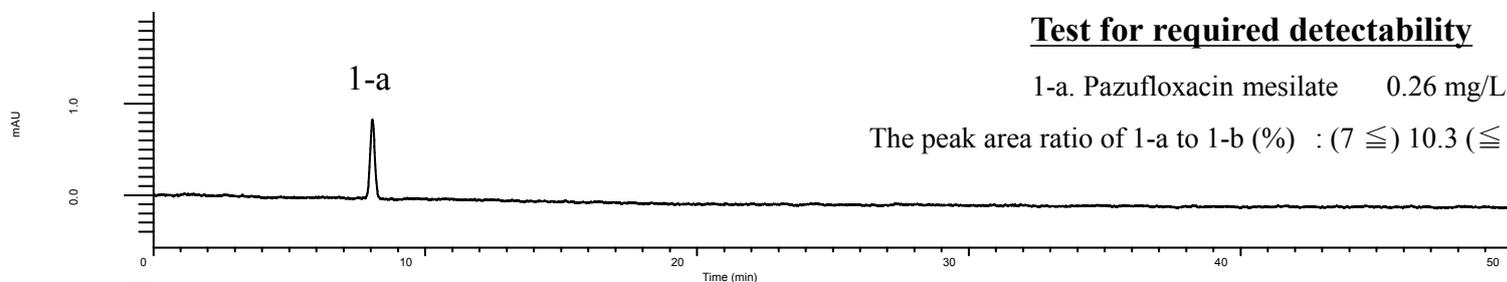
(Under the Condition of the draft for the Japanese Pharmacopoeia)

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 (%) : $(7 \leq) 10.3 (\leq 13)$



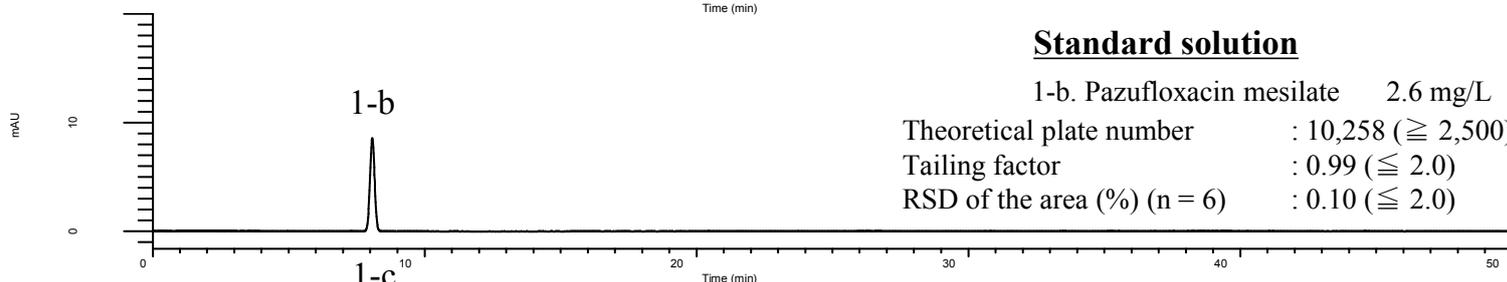
Standard solution

1-b. Pazufloxacin mesilate 2.6 mg/L

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

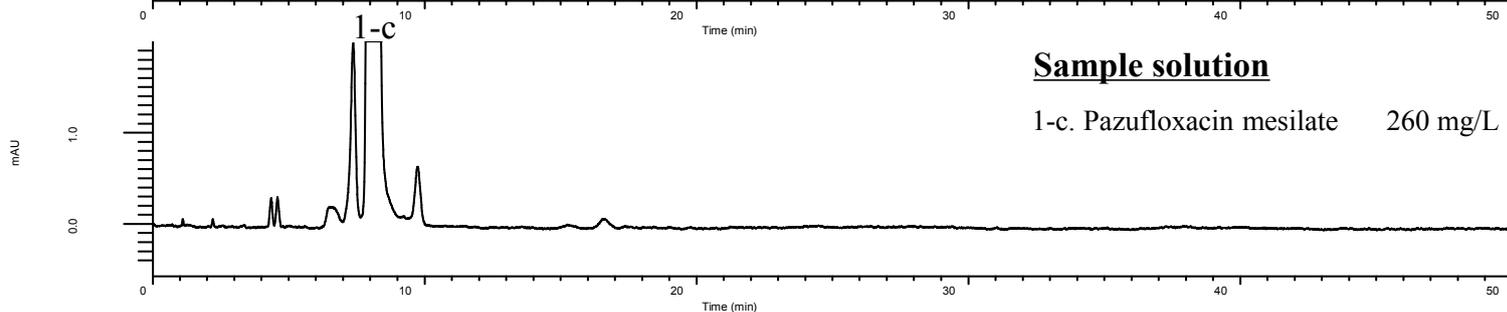
Tailing factor : $0.99 (\leq 2.0)$

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 μ 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 μ 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).