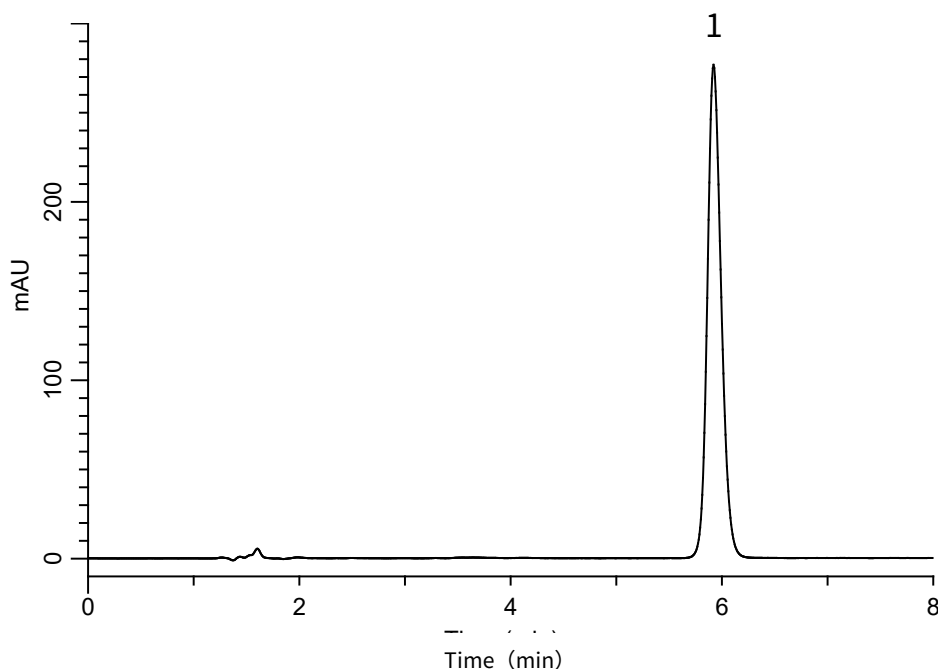


Analysis of Epinastine hydrochloride

(Under the Condition of the Japanese Pharmacopoeia,
Epinastine Hydrochloride Tablets)

Data No. LB152-0894



Conditions

System : GL-7400 HPLC system
Column : Inertsil C8-4
(5 μ m, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020-04085
Eluent : A) CH₃CN
B) Solution*
A/B = 26/74, v/v
Flow Rate : 1.15 mL/min
Col. Temp. : 30 °C
Detection : UV 220 nm (GL-7452 PDA Detector)
Injection Vol. : 10 μ L
Sample : Standard

Analyte:

1. Epinastine hydrochloride 100 mg/L

Theoretical plates : 10,021 ($\geq 6,000$)
Tailing factor : 1.17 (≤ 1.5)

*Add 120.1 g of acetic acid (100) to 500 mL of water. (Solution A)
Add 202.4 g of triethylamine to Solution A by degrees.
Add water to make up to 1000 mL. (Solution B)
Add 975 mL of water to 25 mL of Solution B.
Adjust pH 5.6 by acetic acid (100).