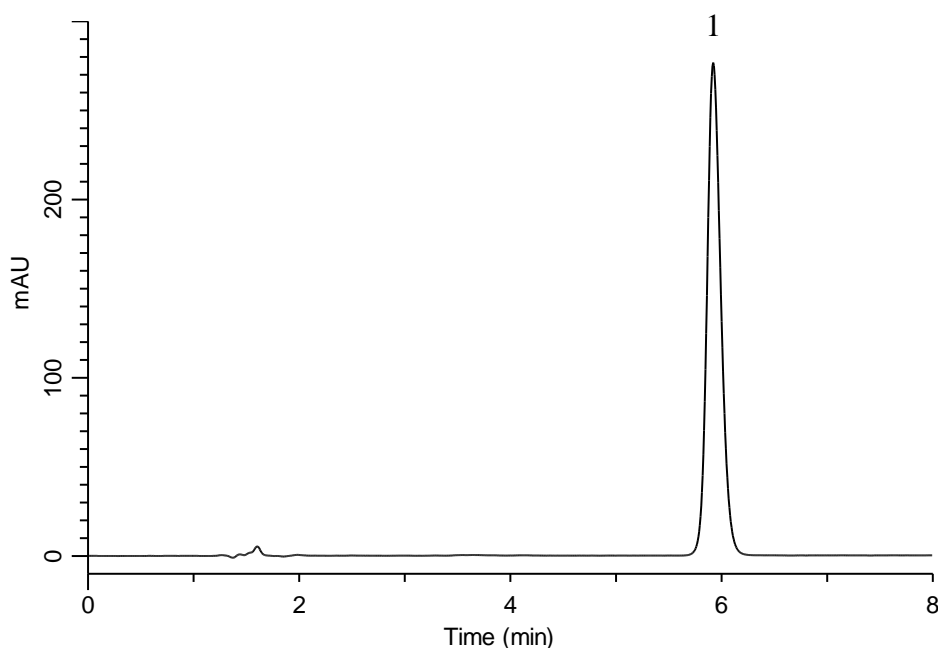


## Analysis of Epinastine hydrochloride

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



### Conditions

**System** : GL-7400 HPLC system  
**Column** : Inertsil C8-4  
 (5  $\mu$  m, 150 x 4.6 mm I.D.)  
**Column Cat. No.** : 5020-04085  
**Eluent** : A) CH<sub>3</sub>CN  
 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  $\mu$  L  
**Sample** : Standard

### Analyte:

1. Epinastine hydrochloride 100 mg/L

Theoretical plates : 10,021 ( $\geq$  6,000)  
 Tailing factor : 1.17 ( $\leq$  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. (SolutionB)  
 Add 975 mL of water to 25 mL of SolutionB.  
 Adjust pH 5.6 by acetic acid (100).