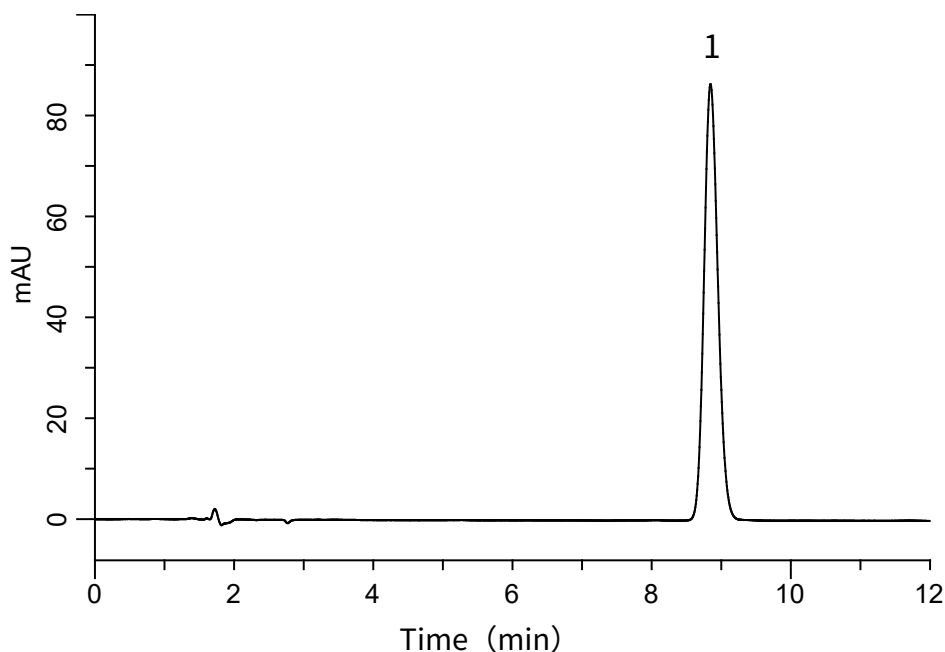


Analysis of Fexofenadine hydrochloride

(Under the Condition of the Japanese Pharmacopoeia)

Data No. LB133-0919



Conditions

System : GL-7400 HPLC system
Column : Inertsil Ph
(5 μ m, 250 x 4.6 mm I.D.)
Column Cat. No. : 5020-01328
Eluent : A) CH₃CN
B) 7.51 g/L NaH₂PO₄ • 2H₂O + 0.84 g/L NaClO₄ in H₂O (pH 2.0, H₃PO₄)
C) Triethylamine
A/B/C = 350/650/3, v/v/v
Flow Rate : 1.8 mL/min
Col. Temp. : 25 °C
Detection : UV 220 nm (GL-7452 PDA Detector)
Injection Vol. : 20 μ L
Sample : Standard

Analyte:

1. Fexofenadine hydrochloride 60 mg/L

Theoretical plates : 9,337 ($\geq 8,000$)

Tailing factor : 1.13 (≤ 2.0)

RSD of the
peak area (%) (n=6) : 0.67 (≤ 1.0)