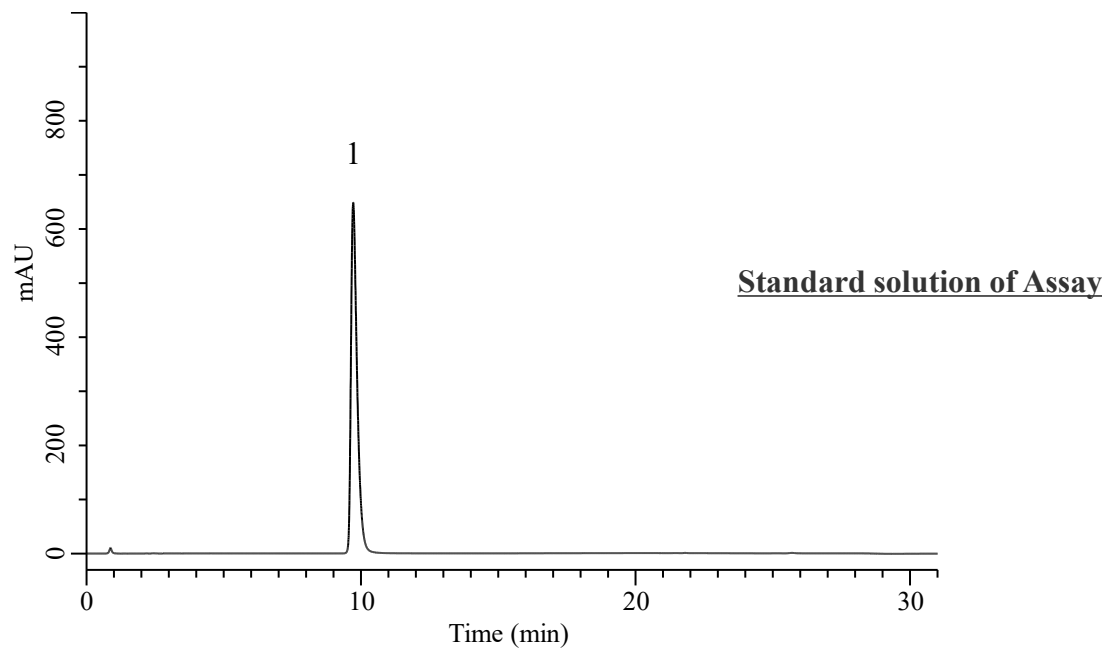


Analysis of Ketotifen fumarate

(Under the Condition of USP-NF 2024 Issue 3, Ketotifen Fumarate, ASSAY)



Conditions

System : Primaide (HITACHI)
Column : InertSustain C18 (GL Sciences Inc.)
(HP 3 μm, 150 x 4.0 mm I.D.)
Column Cat. No. : 5020-90877
Eluent : A) 0.035%TEA in CH₃OH
B) 0.035%TEA in H₂O

Time (min)	A (vol %)	B (vol %)
0	60	40
12	60	40
20	90	10
25	90	10
26	60	40
31	60	40

Flow Rate : 1.0 mL/min
Col. Temp. : 40 °C
Detection : UV 297 nm (Primaide 1410 UV)
Injection Vol. : 20 μL
Sample : Standard in CH₃OH/H₂O = 50/50, v/v

Analyte:
1. Ketotifen fumarate 0.3 mg/mL

Tailing factor : 1.65 (≦ 2.0)

RSD of the peak area (%)(n=6) : 0.357 (≦ 0.73)