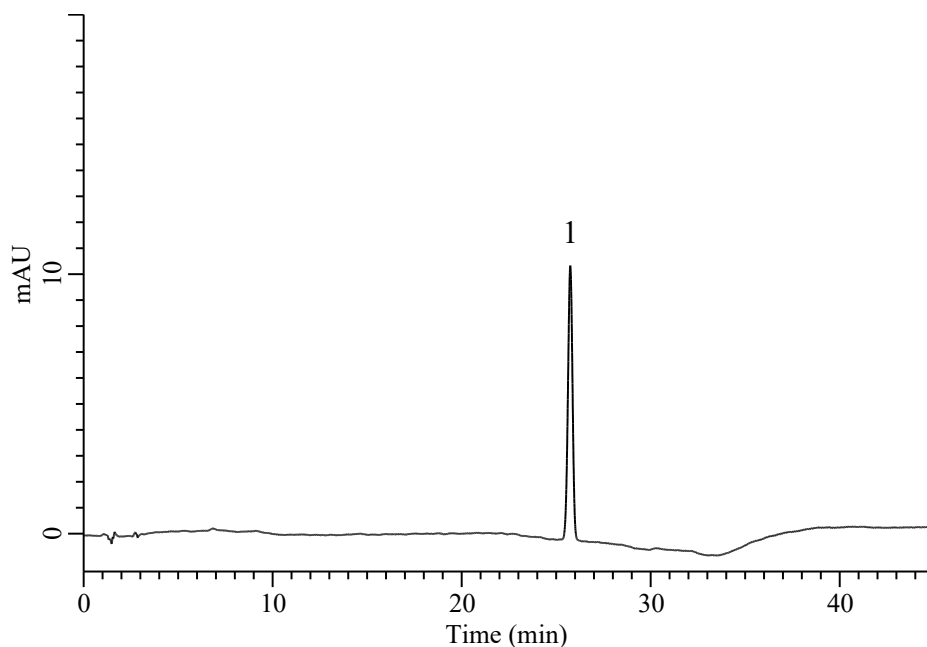


Analysis of Terbinafine hydrochloride

(Under the Condition of USP41-NF36, Terbinafine Tablets, IMPURITIES (LIMIT OF TERBINAFINE DIMER))



Conditions

System : Primaide (HITACHI)
Column : Inertsil Hybrid-C18 (GL Sciences Inc.)
 (5 μ m, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020-76016
Eluent : A) Solution A*
 B) Solution B**

Time(min)	A%	B%
0	60	40
8	70	30
18	70	30
24	84	16
26	95	5
30	100	0
37	60	40
45	60	40

Flow Rate : 1.0 mL/min
Col. Temp. : 52 °C
Detection : UV 280 nm (Primaide 1435 DAD)
Injection Vol. : 100 μ L
Sample : Standard in CH₃CN/H₂O = 4/1, v/v

Analyte:

1. Terbinafine hydrochloride 1.4 μ g/mL

Tailing factor : 0.96 ($\leq$ 2.0)

RSD of the peak area (%)(n=6) : 0.45 ($\leq$ 10.0)

* : 1 mL/L of triethylamine in CH₃CN/H₂O = 19/1, v/v

** : 1 mL/L of triethylamine in H₂O