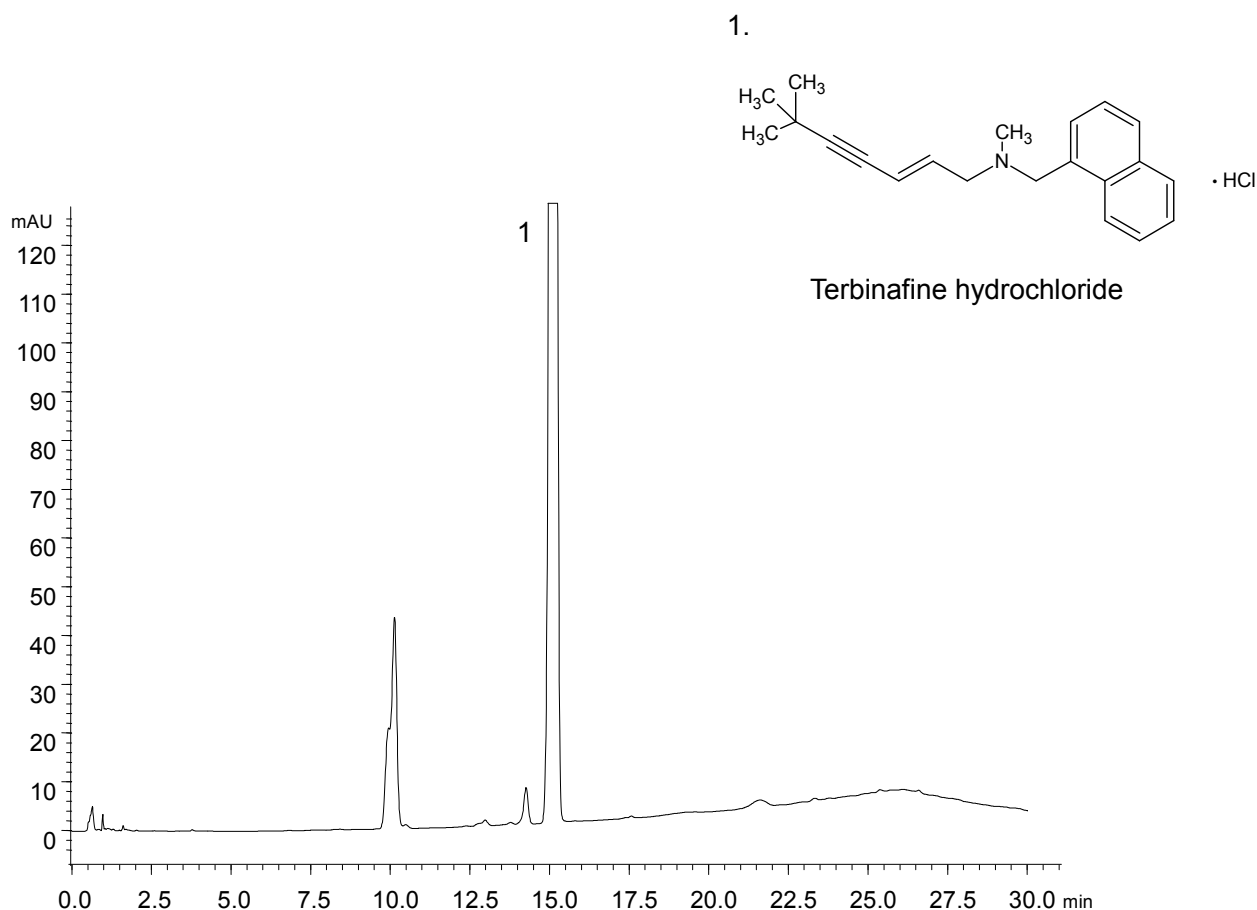


テルビナフィン塩酸塩
Terbinafine hydrochloride

A110708A



Column : YMC-Pack Pro C18 RS (5 μm, 8 nm)
 150 × 3.0 mm I.D.
 Eluent : A) methanol/acetonitrile/buffer* (42/28/30)
 B) methanol/acetonitrile/buffer* (57/38/5)
 0%B(0-4 min), 0-100%B(4-25 min), 100%B(25-30 min)
 * triethylamine(1 → 500), adjust pH 7.5 with 1M acetic acid
 Flow rate : 1.3 mL/min
 Temperature : 40°C
 Detection : UV at 280 nm
 Injection : 20 μL
 Sample : terbinafine hydrochloride 1.0 mg/mL in 50% acetonitrile
 (expose to UV light at 254 nm for 1 hour)
 (The Japanese Pharmacopoeia 16th ; Related substances)

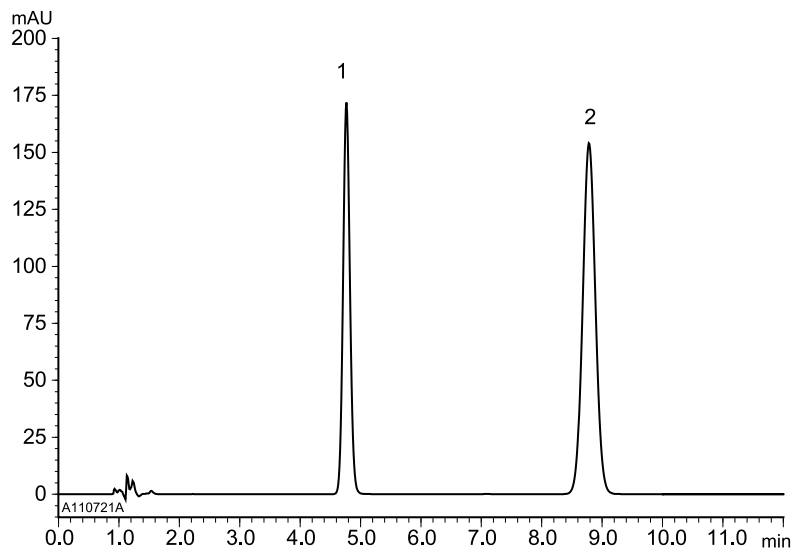
テルビナフィン塩酸塩液・スプレー・クリーム

Terbinafine hydrochloride solution, spray and cream

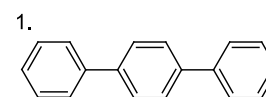
A110721C

A) System suitability solution*

(0.0175 mg/mL *p*-Terphenyl, 0.2 mg/mL Terbinafine hydrochloride)

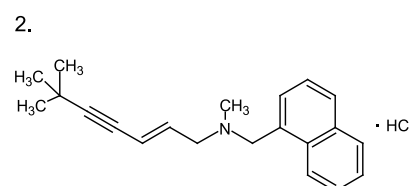
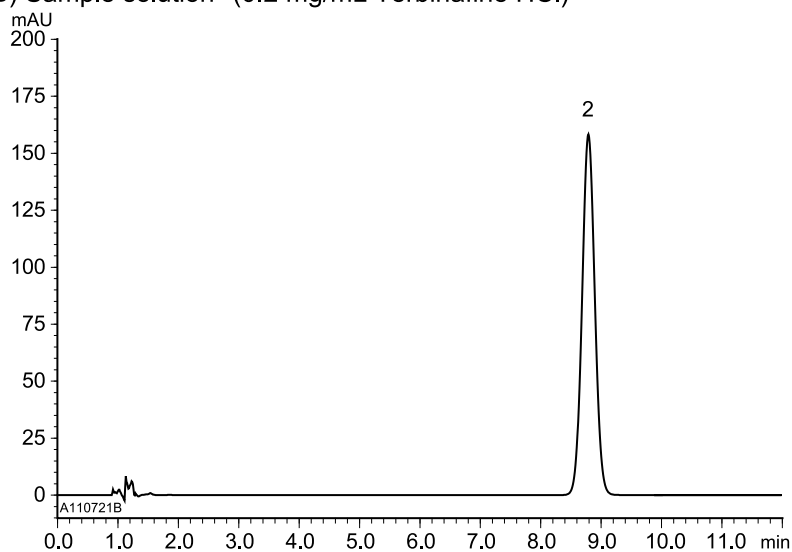


| | System suitability requirement | result |
|------------------|--------------------------------|--------|
| Resolution (1,2) | ≥ 6 | 13.5 |



p-Terphenyl

B) Sample solution* (0.2 mg/mL Terbinafine HCl)



Terbinafine hydrochloride

*System suitability solution was prepared from Terbinafine HCl supplied as a reagent for laboratory use.
Sample solution was prepared from Terbinafine HCl solution.

Column : YMC-Pack ODS-A (5 μm, 30 nm)
125 X 4.0 mm I.D.

Eluent : acetonitrile/tetrahydrofuran/buffer* (40/20/40)
※ Dissolve 9 mL of 10% tetramethylammonium hydroxide in 2000 mL water,
adjust pH 8.0 with H₃PO₄ (1→25)

Flow rate : 1.1 mL/min (adjust the flow rate so that the retention time of terbinafine is about 8.5 min)

Temperature : 25°C

Detection : UV at 282 nm

Injection : 10 μL

(The Japanese Pharmacopoeia 16th ; Assay)