

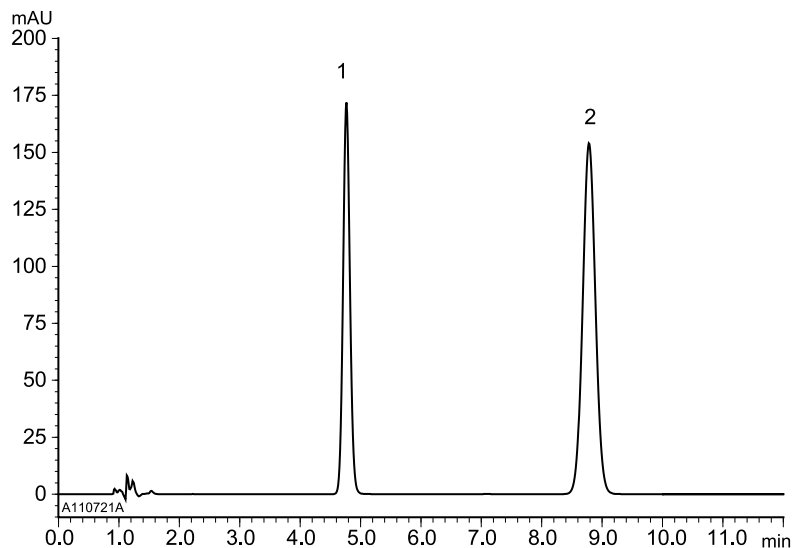
テルビナフィン塩酸塩液・スプレー・クリーム

Terbinafine hydrochloride solution, spray and cream

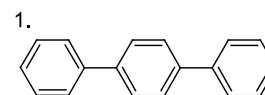
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A) System suitability solution*

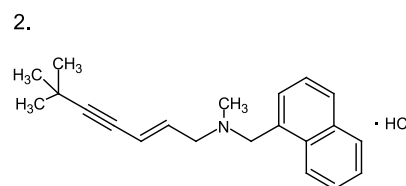
(0.0175 mg/mL *p*-Terphenyl, 0.2 mg/mL Terbinafine hydrochloride)



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

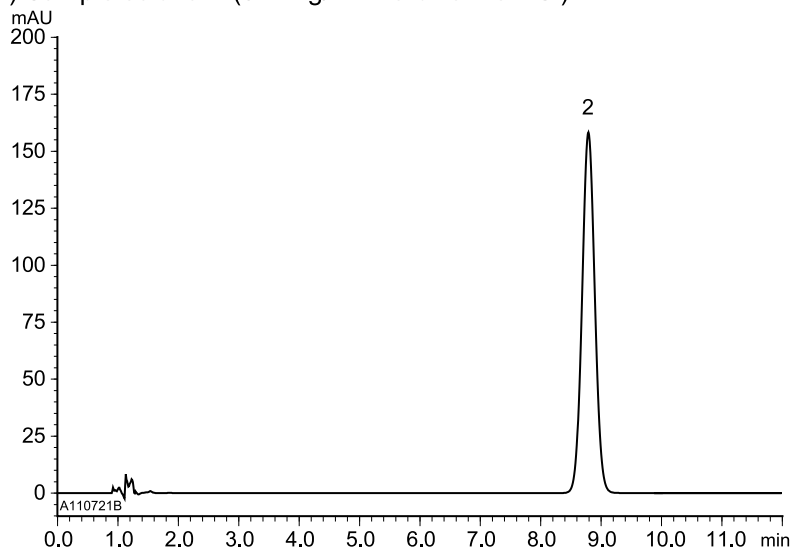


p-Terphenyl



Terbinafine hydrochloride

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



*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)