

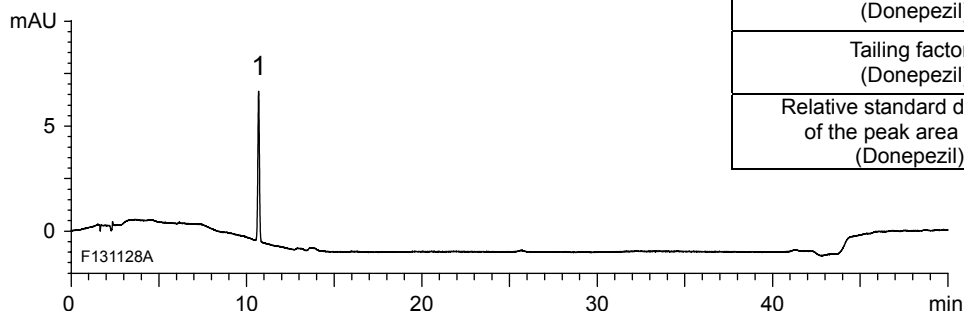
ドネペジル塩酸塩 (米国薬局方記載条件)

Donepezil hydrochloride (The United States Pharmacopeia)

F131216A

(A) Standard solution*

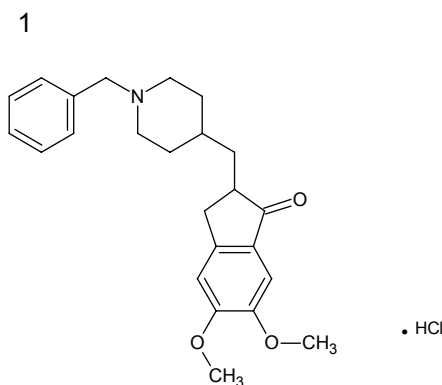
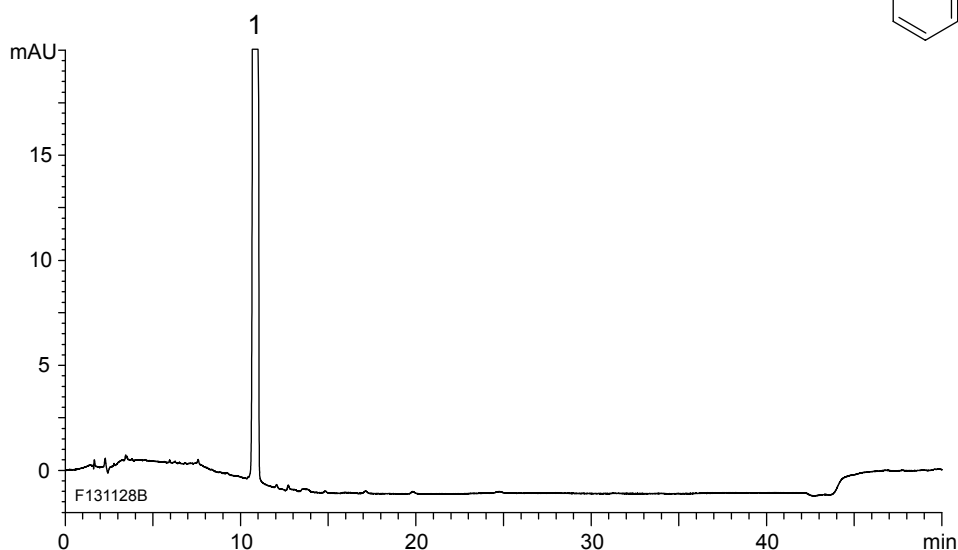
(0.01 mg/mL Donepezil hydrochloride)



	System suitability requirement	Result
Theoretical plate number (Donepezil)	≥ 40000	64400
Tailing factor (Donepezil)	≤ 1.5	0.99
Relative standard deviation of the peak area (n=5) (Donepezil)	$\leq 2.0\%$	0.47%

(B) Sample solution*

(1.0 mg/mL Donepezil hydrochloride)



Column : YMC-Triart C18 (5 μ m, 12 nm)
250 X 4.6 mm I.D.

Eluent : A) 0.1% phosphoric acid in water, adjust pH 6.5 with triethylamine
B) acetonitrile
25-60%B (0-10 min), 60%B (10-40 min), 60-25%B (40-41 min), 25%B (41-50 min)

Flow rate : 1.5 mL/min

Temperature : 50°C

Detection : UV at 286 nm

Injection : 20 μ L

(The United States Pharmacopeia 37th; Organic impurities, Procedure 2)

* All standard and sample solutions were prepared from Donepezil hydrochloride supplied as a reagent for laboratory use.