

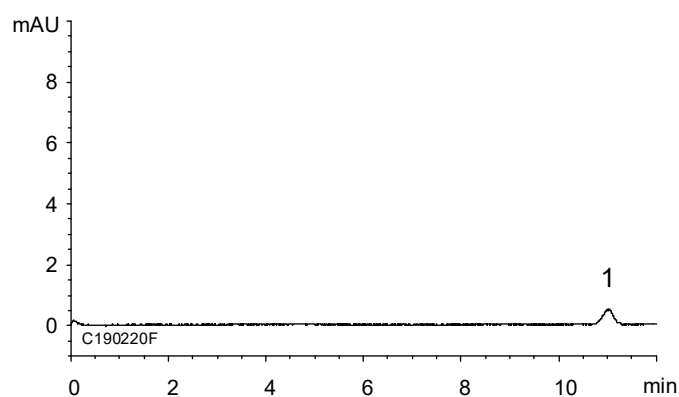
ドネペジル塩酸塩 (日本薬局方記載条件)

Donepezil hydrochloride (The Japanese Pharmacopoeia)

C190221A

(A) Standard solution for Related substances<sup>\*3</sup>

(0.4 µg/mL Donepezil hydrochloride)



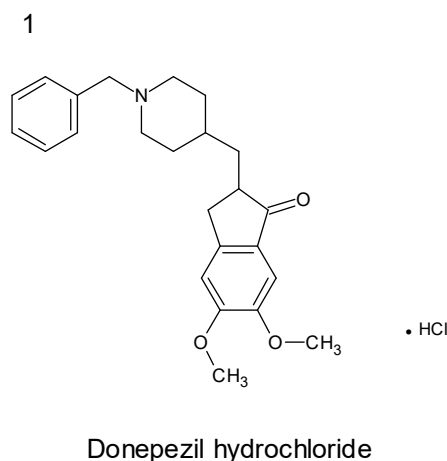
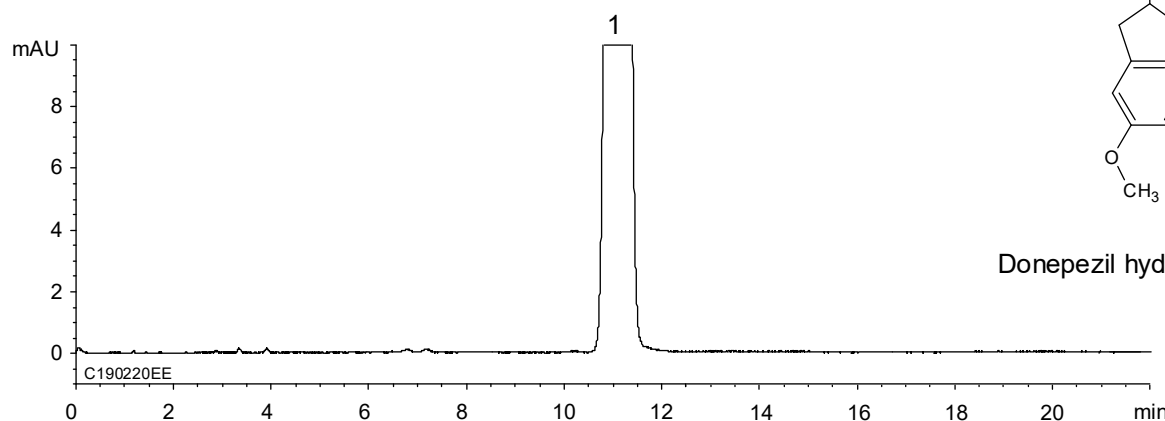
	System suitability requirement	Result <sup>*2</sup> (0.4 µg/mL)	Result <sup>*1</sup> (0.4 mg/mL)
Theoretical plate number (Donepezil)	≥ 5000	12100	10500
Tailing factor (Donepezil)	≤ 1.5	1.07	1.26
Relative standard deviation of the peak area (n=6) (Donepezil)	≤ 1.0 % <sup>*1</sup>	0.71 %	0.04%
	≤ 2.0 % <sup>*2</sup>		

<sup>\*1</sup> Assay  
<sup>\*2</sup> Related substances

(B) Sample solution for Related substances<sup>\*3</sup>

Standard solution for Assay<sup>\*3</sup>

(0.4 mg/mL Donepezil hydrochloride)



Column : Hydrosphere C18 (5 µm, 12 nm)  
150 X 4.6 mm I.D.

Eluent : acetonitrile/water/perchloric acid (350/650/1)  
containing 2.5 g of sodium 1-decansulfonate

Flow rate : 1.85 mL/min  
(adjust the flow rate so that the retention time of donepezil is about 11 min)

Temperature : 35°C

Detection : UV at 271 nm

Injection : 20 µL

(The Japanese Pharmacopoeia 16th; Assay, Related substances)

<sup>\*3</sup> All standard and sample solution were prepared from Donepezil hydrochloride supplied as a reagent for laboratory use.