

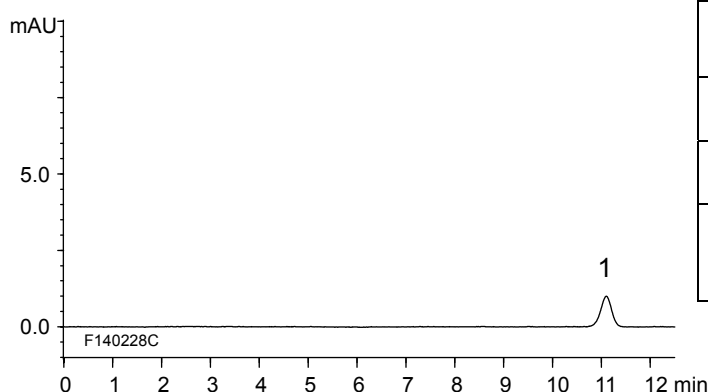
ドネペジル塩酸塩 (日本薬局方記載条件)

Donepezil hydrochloride (The Japanese Pharmacopoeia)

F140312A

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

(0.4 µg/mL Donepezil hydrochloride)

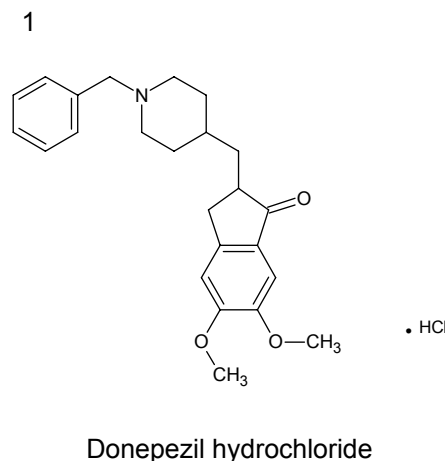
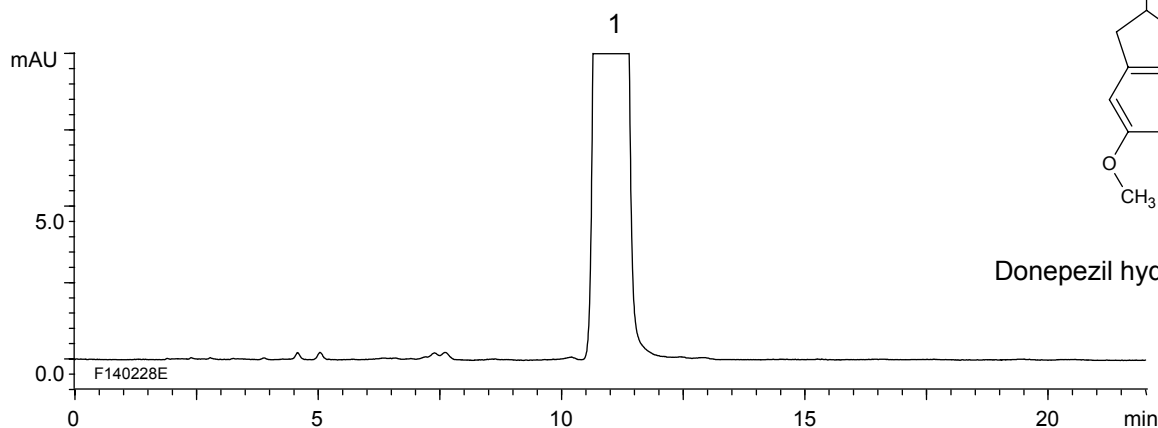


	System suitability requirement	Result
Theoretical plate number (Donepezil)	≥ 5000	11700
Tailing factor (Donepezil)	≤ 1.5	0.98
Relative standard deviation of the peak area (n=6) (Donepezil)	≤ 1.0 %* <sup>1</sup> ≤ 2.0 %* <sup>2</sup>	0.68 %

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

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

(0.4 mg/mL Donepezil hydrochloride)



Column : YMC-Pack ODS-A (5 µm, 30 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 : 0.9 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.