

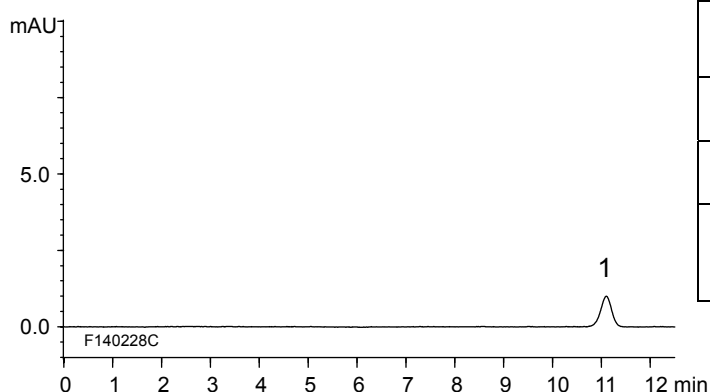
ドネペジル塩酸塩 (日本薬局方記載条件)

Donepezil hydrochloride (The Japanese Pharmacopoeia)

F140312A

(A) Standard solution*³

(0.4 µg/mL Donepezil hydrochloride)

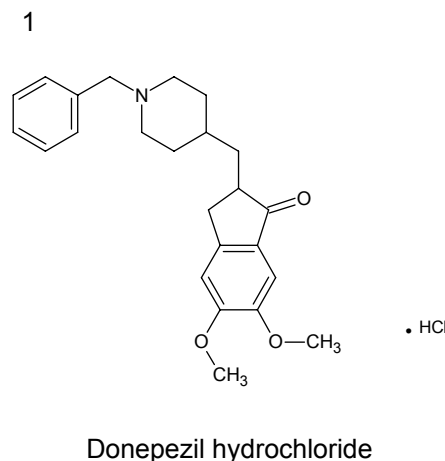
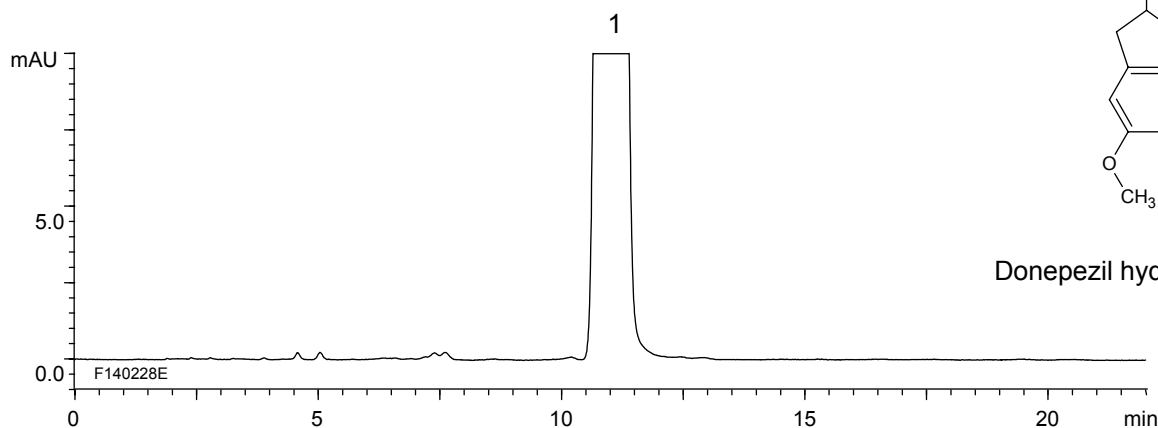


	System suitability requirement	Result
Theoretical plate number (Donepezil)	≥ 5000	11700
Tailing factor (Donepezil)	≤ 1.5	0.98
Relative standard deviation of the peak area (n=6) (Donepezil)	≤ 1.0 %* ¹ ≤ 2.0 %* ²	0.68 %

*¹ Assay
*² Related substances

(B) Sample solution*³

(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)

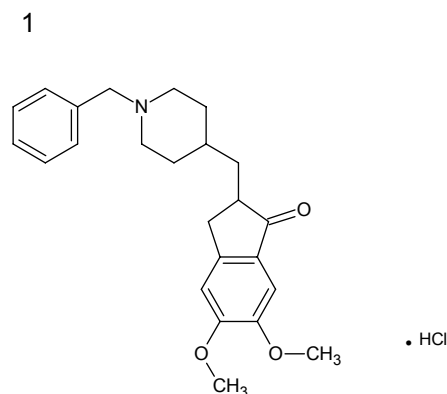
*³ All standard and sample solution were prepared from Donepezil hydrochloride supplied as a reagent for laboratory use.

ドネペジル塩酸塩錠・細粒（日本薬局方記載条件）
Donepezil hydrochloride tablets and fine granules
(The Japanese Pharmacopoeia)

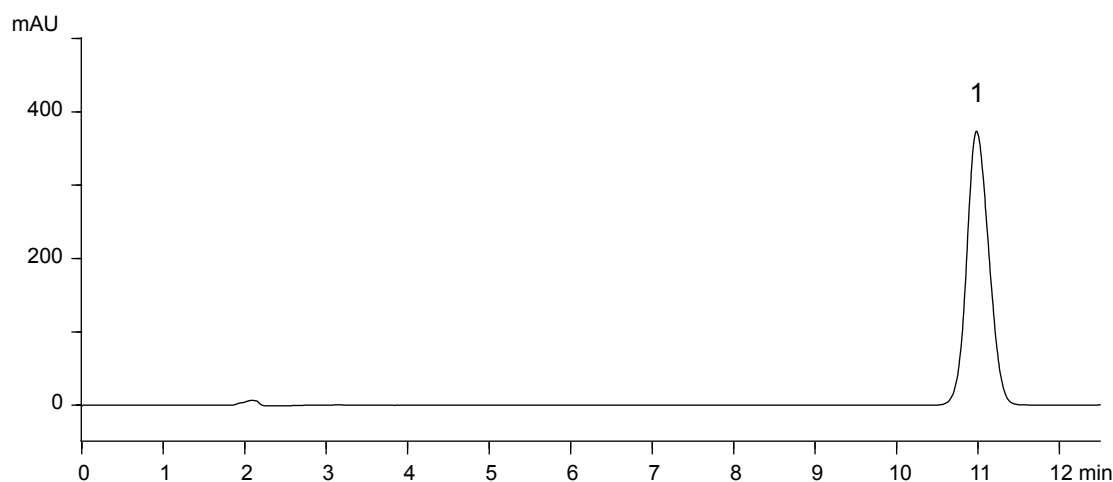
F140228D

Standard solution*
(0.2 mg/mL Donepezil hydrochloride)

	System suitability requirement	Result
Theoretical plate number (Donepezil)	≥ 4000	7600
Tailing factor (Donepezil)	≤ 1.5	1.13
Relative standard deviation of the peak area (n=6) (Donepezil)	$\leq 1.0\%$	0.10%



Donepezil hydrochloride



Column : YMC-Pack ODS-A (5 μ m, 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 μ L

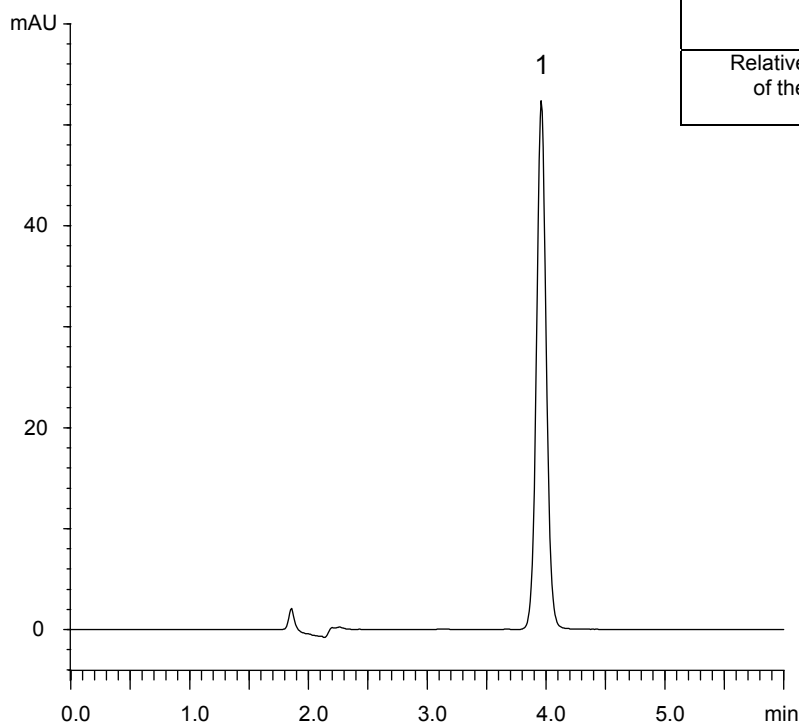
(The Japanese Pharmacopoeia 16th; Uniformity of dosage units)

* Standard solution was prepared from Donepezil hydrochloride supplied as a reagent for laboratory use.

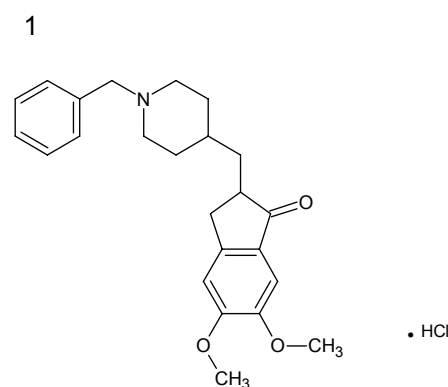
ドネペジル塩酸塩錠・細粒（日本薬局方記載条件）
Donepezil hydrochloride tablets and fine granules
(The Japanese Pharmacopoeia)

F140228A

Standard solution*
(3.3 µg/mL Donepezil hydrochloride)



	System suitability requirement	Result
Theoretical plate number (Donepezil)	≥ 5000	9400
Tailing factor (Donepezil)	≤ 1.5	1.09
Relative standard deviation of the peak area (n=6) (Donepezil)	≤ 1.0 %	0.16 %



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)
Flow rate : 1.0 mL/min
(adjust the flow rate so that the retention time of donepezil is about 4 min)
Temperature : 35°C
Detection : UV at 271 nm
Injection : 50 µL
(The Japanese Pharmacopoeia 16th; Dissolution)

* Standard solution was prepared from Donepezil hydrochloride supplied as a reagent for laboratory use.