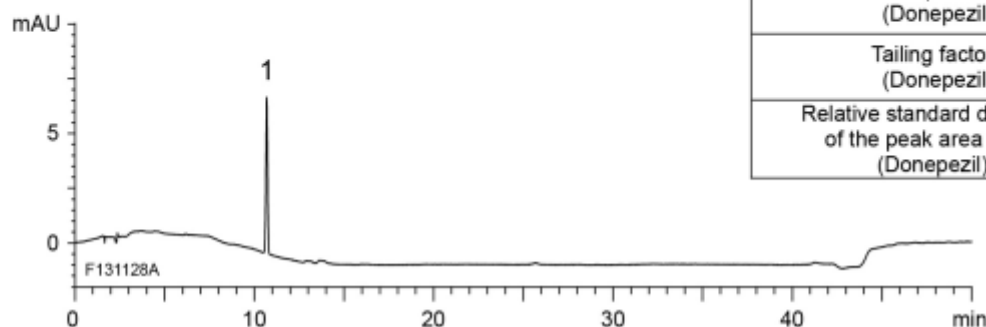
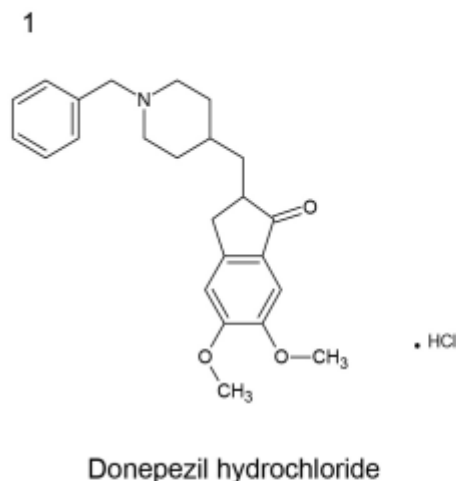
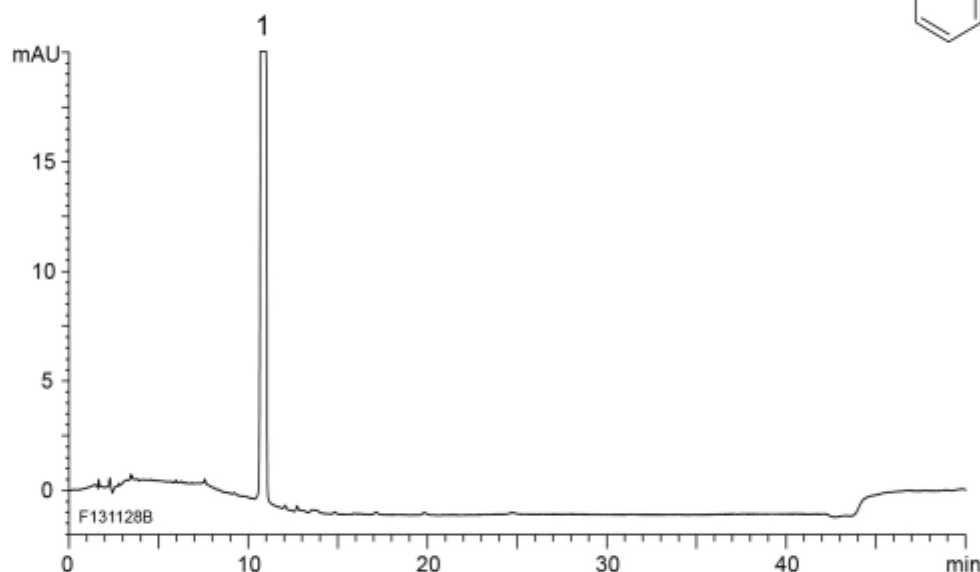


(A) Standard solution*
(0.01 mg/mL Donepezil hydrochloride)



| | 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.