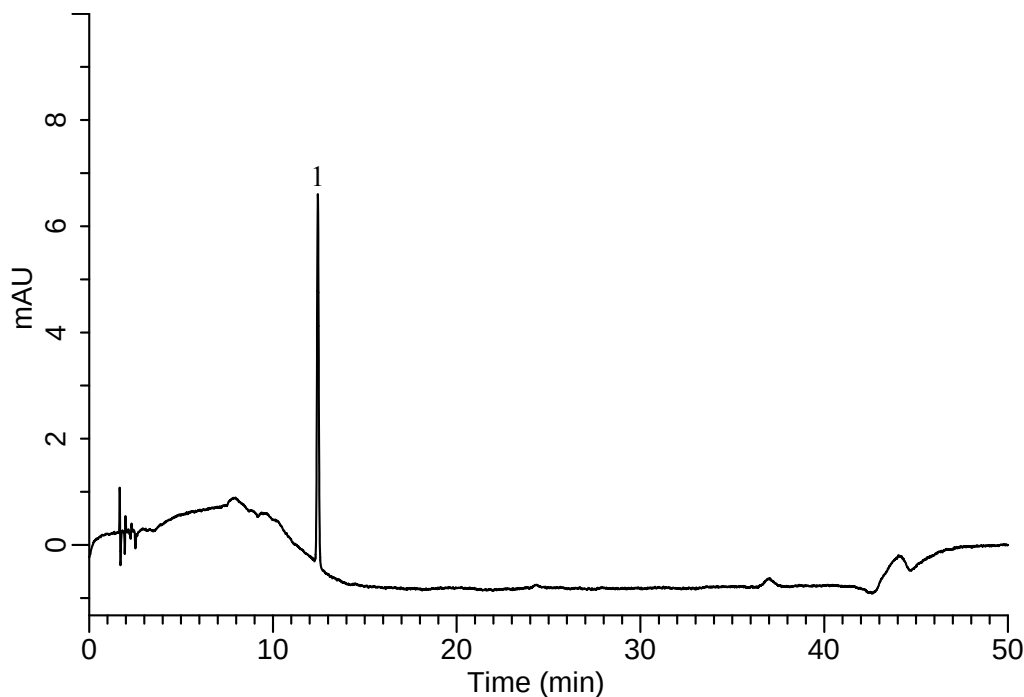


Analysis of Donepezil Hydrochloride – Impurities

(USP Authorized Pending Monographs ver. 2)

Data No. LA898-0811



Conditions

System : GL-7400 HPLC system
Column : Inertsil ODS-3 (5 µm, 250 x 4.6 mm I.D.)
Column Cat. No. : 5020-01732
Eluent : A) CH₃CN
 : B) Aqueous solution of phosphate acid*
 : A/B = 25/75 -10 min- 60/40 -30 min-
 : 60/40 -1 min- 25/75 -9 min- 25/75, v/v
Flow rate : 1.5 mL/min
Col. Temp. : 50 °C
Detection : UV 286 nm (GL-7450 UV Detector)
Injection Vol. : 20 µL

Analyte :

1. Donepezil Hydrochloride (10 µg/mL)

Theoretical plates : 65356 (> 40000)
Tailing factor : 0.99 (< 1.5)
Relative standard deviation (N = 5) : 0.30 % (< 2 %)

*Aqueous solution of phosphate acid: Add 1mL of H₃PO₄ in 1L of water, and mix.
Adjust the pH of this solution to 6.5 with triethylamine.