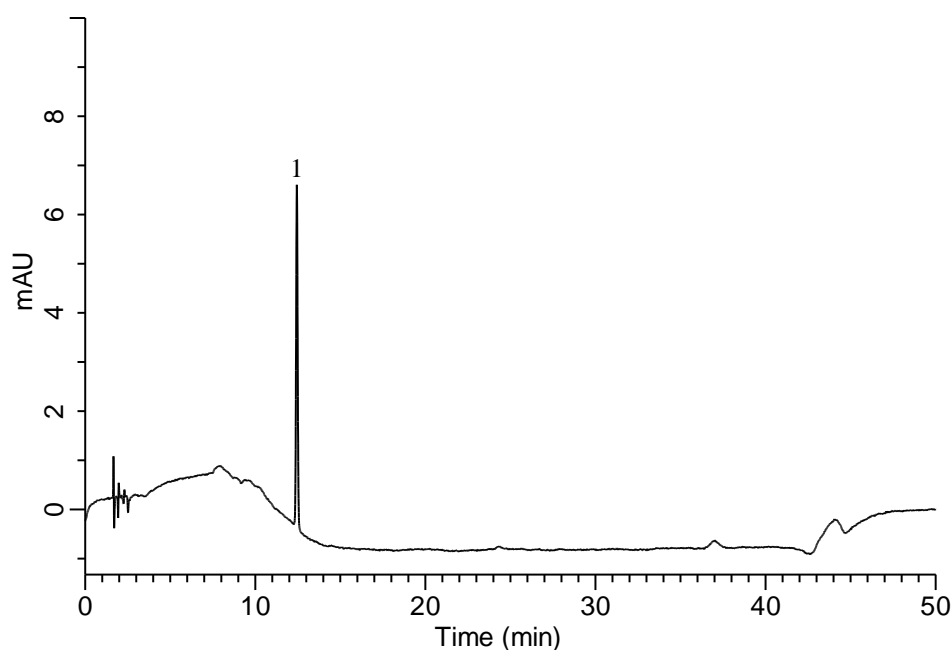


## Analysis of Donepezil Hydrochloride – Impurities

(USP Authorized Pending Monographs ver. 2)



### Conditions

**System** : GL-7400 HPLC system  
**Column** : Inertsil ODS-3 (5  $\mu$ m, 250 x 4.6 mm I.D)  
**Column Cat. No.** : 5020-01732  
**Eluent** : A) CH<sub>3</sub>CN  
           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  $\mu$ L

### Analyte :

1. Donepezil Hydrochloride (10  $\mu$ g/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 H<sub>3</sub>PO<sub>4</sub> in 1L of water, and mix.  
Adjust the pH of this solution to 6.5 with triethylamine.