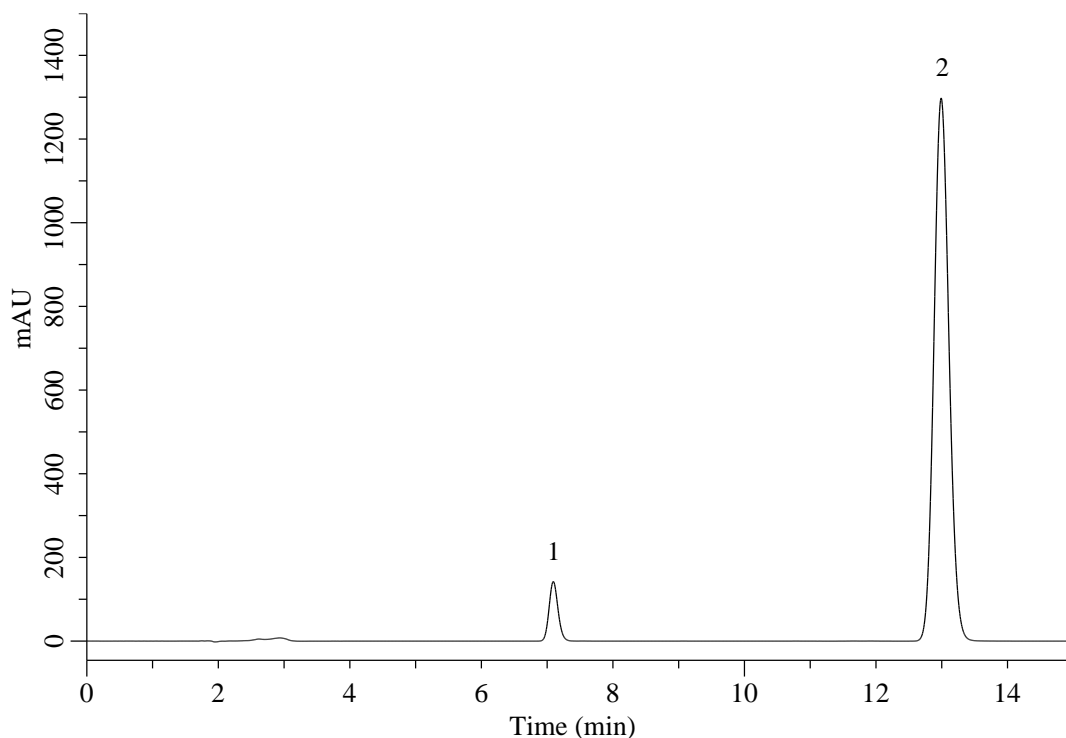


## Analysis of Tolvaptan

(Under the Condition of the draft for the Japanese Pharmacopoeia 18<sup>th</sup> Supplement II)



### Conditions

**System** : Primaide HPLC system (HITACHI)  
**Column** : Inertsil ODS-4 (GL Sciences Inc.)  
 (5  $\mu$  m, 150 x 6.0 mm I.D.)  
**Column Cat. No.** : 5020-03955  
**Eluent** : A) CH<sub>3</sub>CN  
 B) H<sub>2</sub>O  
 C) H<sub>3</sub>PO<sub>4</sub>  
 A/B/C = 600/400/1, v/v/v  
**Flow Rate** : 1.1 mL/min  
**Col. Temp.** : 25 °C  
**Detection** : UV 254 nm  
**Injection Vol.** : 5  $\mu$  L  
**Sample** : Standard

### Analyte:

1. Tolvaptan 100 mg/L  
 2. Hexyl 4-hydroxybenzoate (I.S.) 60 mg/L

Resolution (1,2) : 17.8 ( $\geq 15$ )  
 RSD of the peak area ratio of 1 to 2 (%) (n=6) : 0.33 ( $\leq 1.0$ )