

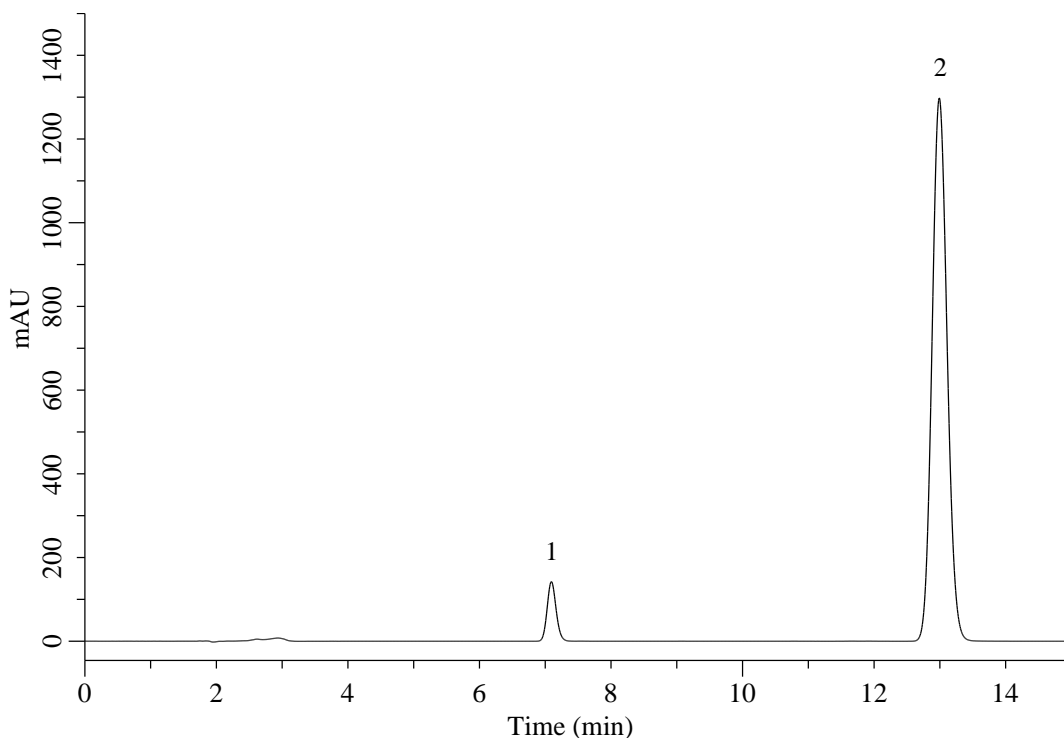
InertSearch for LC

Inertsil Applications

Analysis of Tolvaptan

(Under the Condition of the draft for the Japanese Pharmacopoeia 18th Supplement II)

Data No. LB848-1140



Conditions

System : Primaide HPLC system (HITACHI)
Column : Inertsil ODS-4 (GL Sciences Inc.)
(5 μ m, 150 x 6.0 mm I.D.)
Column Cat. No. : 5020-03955
Eluent : A) CH₃CN
B) H₂O
C) H₃PO₄
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 μ L
Sample : Standard

Analyte:

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

Resolution (1,2) : 17.8 (≥ 15)
RSD of the peak area ratio of 1 to 2
(%)(n=6) : 0.33 (≤ 1.0)