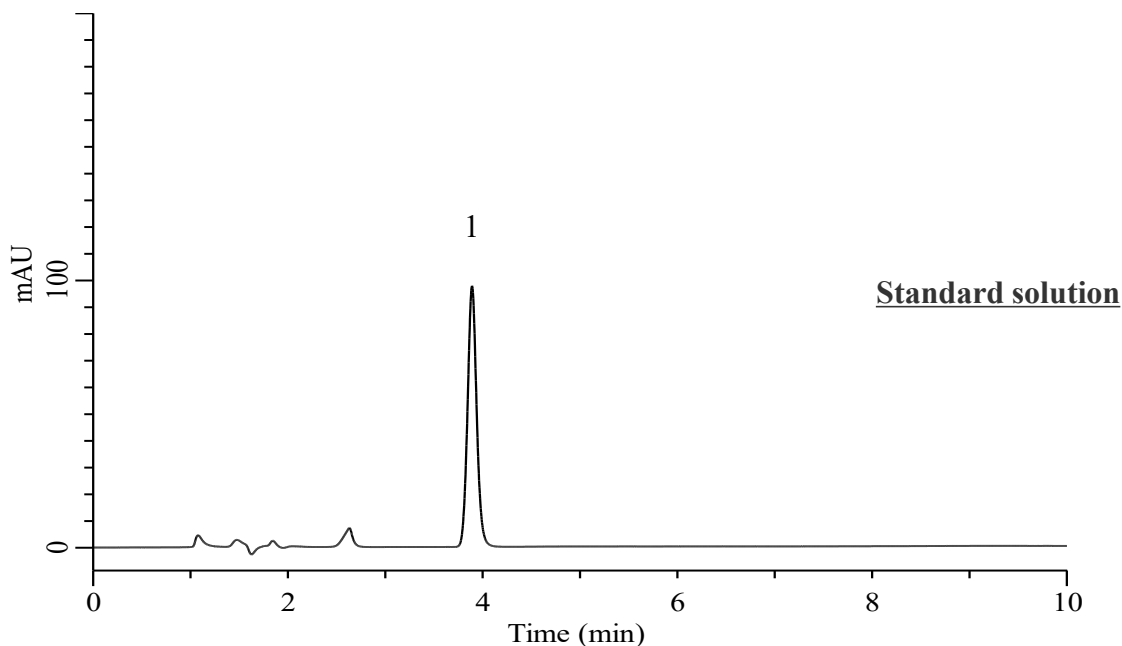


Analysis of Pregabalin

(Under the Condition of draft for USP PF52(4), Pregabalin Capsules, ASSAY)



Conditions

System : Primaide (HITACHI)
Column : Inertsil ODS-3 (GL Sciences Inc.)
 (5 μ m, 250 x 4.6 mm I.D.)
Column Cat. No. : 5020-01732
Eluent : CH₃CN/Buffer*=10/90, v/v
Flow Rate : 1.5 mL/min
Autosampler : 20 °C
Col. Temp. : 35 °C
Detection : UV 205 nm (Primaide 1410 UV)
Injection Vol. : 50 μ L
Sample : Standard in Buffer*

Analyte:

1. (S)-Pregabalin 0.6 mg/mL

Tailing factor : (0.8 $\leq$) 1.09 ($\leq$ 1.8)

RSD of
the peak area (%) (n=6) : 0.07 ($\leq$ 1.0)

* : Dissolve 5.6 g of ammonium phosphate, dibasic in 1000 mL of water. Adjust with phosphoric acid to a pH of 6.5.