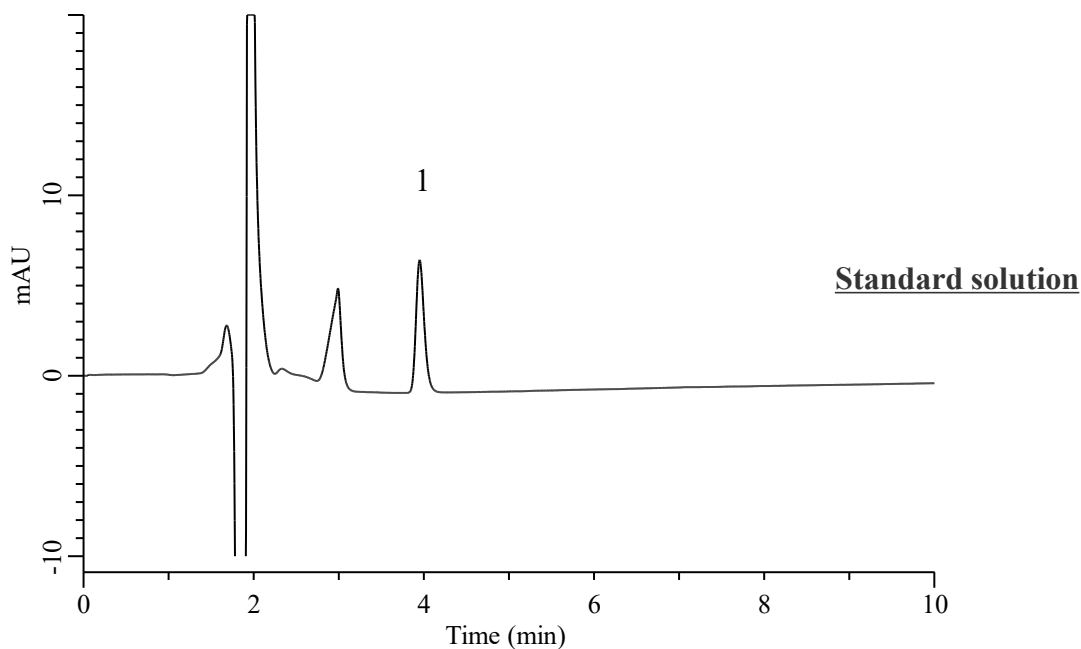


Analysis of Pregabalin

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



Conditions

System : Chromaster PLUS (HITACHI)
Column : InertSustain C18 (GL Sciences Inc.)
 (5 μ m, 250 x 4.6 mm I.D.)
Column Cat. No. : 5020-07346
Eluent : CH₃CN/Buffer*=10/90, v/v
Flow Rate : 1.5 mL/min
Autosampler : 20 °C
Col. Temp. : 35 °C
Detection : UV 210 nm (Chromaster 5420 UV-VIS)
Injection Vol. : 100 μ L
Sample : Standard in (0.06 N HCl in H₂O)

Analyte:

1. (S)-Pregabalin 28 μ g/mL

Tailing factor : 1.26 ($\leq$ 2.0)

RSD of
the peak area (%)(n=6) : 0.66 ($\leq$ 2.0)

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