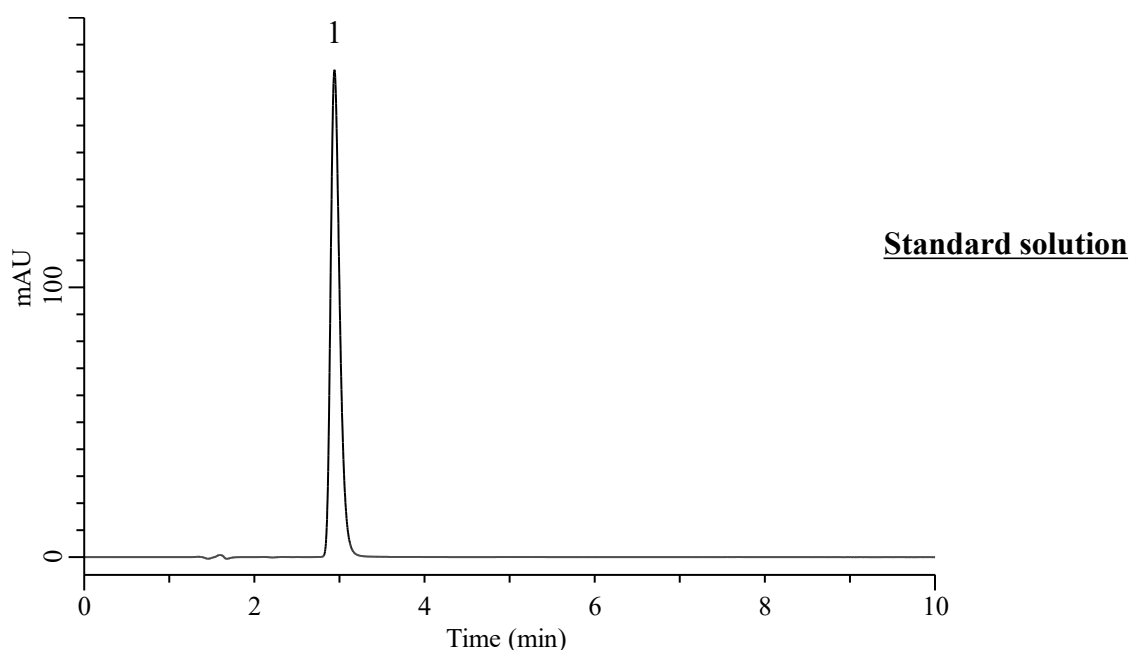


Analysis of Vortioxetine

(Under the Condition of draft for USP PF52(1), Vortioxetine Tablets, ASSAY)



Conditions

System : Primaide (HITACHI)
Column : InertSustain C18 (GL Sciences Inc.)
 (5 μ m, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020-07345
Eluent : Solution A/Buffer*= 60/40, v/v
Flow Rate : 1.0 mL/min
Col. Temp. : 30 °C
Detection : UV 240 nm (Primaide 1410 UV)
Injection Vol. : 5 μ L
Sample : Standard in CH₃CN/H₂O= 50/50, v/v

Analyte:

1. Vortioxetine 0.13 mg/mL

Tailing Factor : (0.8 \leq) 1.37 (\leq 1.8)

RSD of the peak area (n=6) : 0.21 (\leq 1.0)

Solution A : CH₃CN/CH₃OH = 80/20, v/v

* : Dissolve 1.54 g of ammonium acetate and 2 mL of triethylamine in 1000 mL of water.
 Adjust with phosphoric acid to a pH of 4.5.