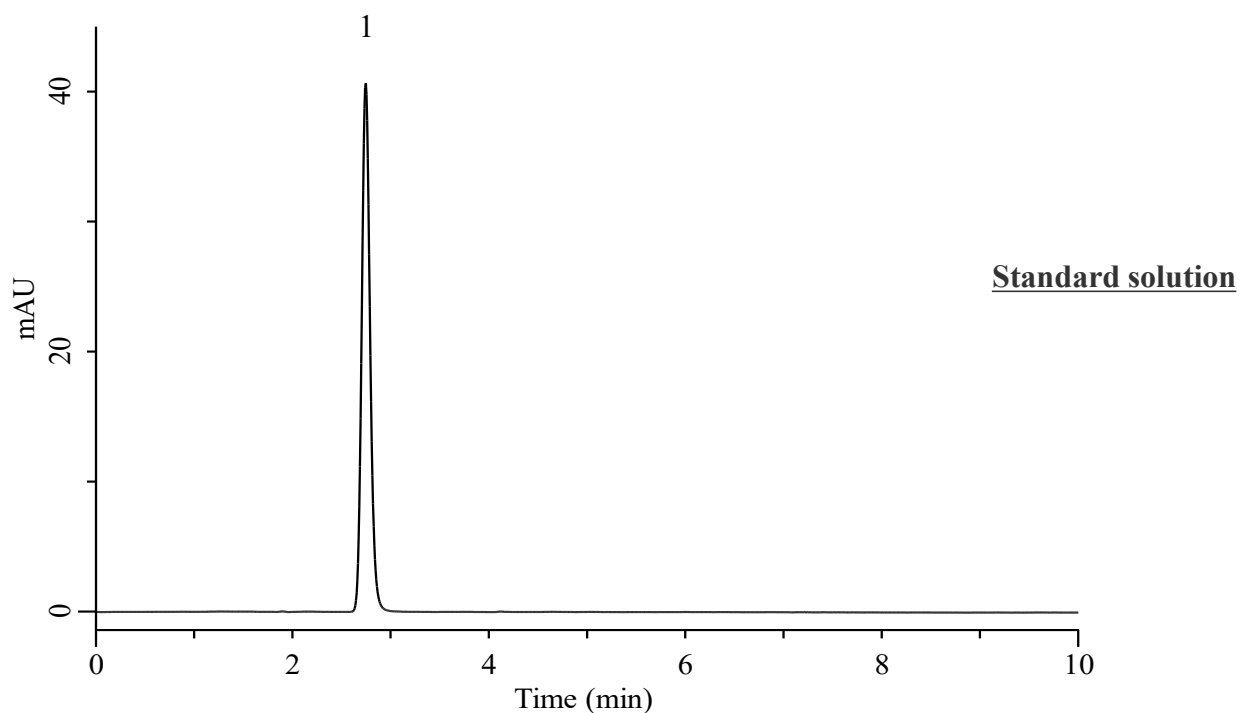


Analysis of Pramipexole dihydrochloride

(Under the Condition of draft for USP PF52(3), Pramipexole Dihydrochloride Tablets, ASSAY)



Conditions

System : Primaide (HITACHI)
Column : InertSustainSwift C18 (GL Sciences Inc.)
 (5 μ m, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020-88026
Eluent : A) CH₃CN/H₂O=80/20, v/v
 B) Solution*
 A/B=30/70, v/v
Flow Rate : 1.0 mL/min
Col. Temp. : 40 °C
Detection : UV 262 nm (Primaide 1430 DAD)
Injection Vol. : 20 μ L
Sample : Standard in Eluent

Analyte:

1. Pramipexole dihydrochloride monohydrate
10 μ g/mL

Tailing factor : 1.04 ($\leq$ 2.0)

RSD of
the peak area (%) (n=6) : 0.19 ($\leq$ 1.0)

* : Dissolve 2.0 g of sodium 1-heptanesulfonate and 2.0 g of sodium acetate in 1000 mL of water.
Adjust with glacial acetic acid to a pH of 6.0.