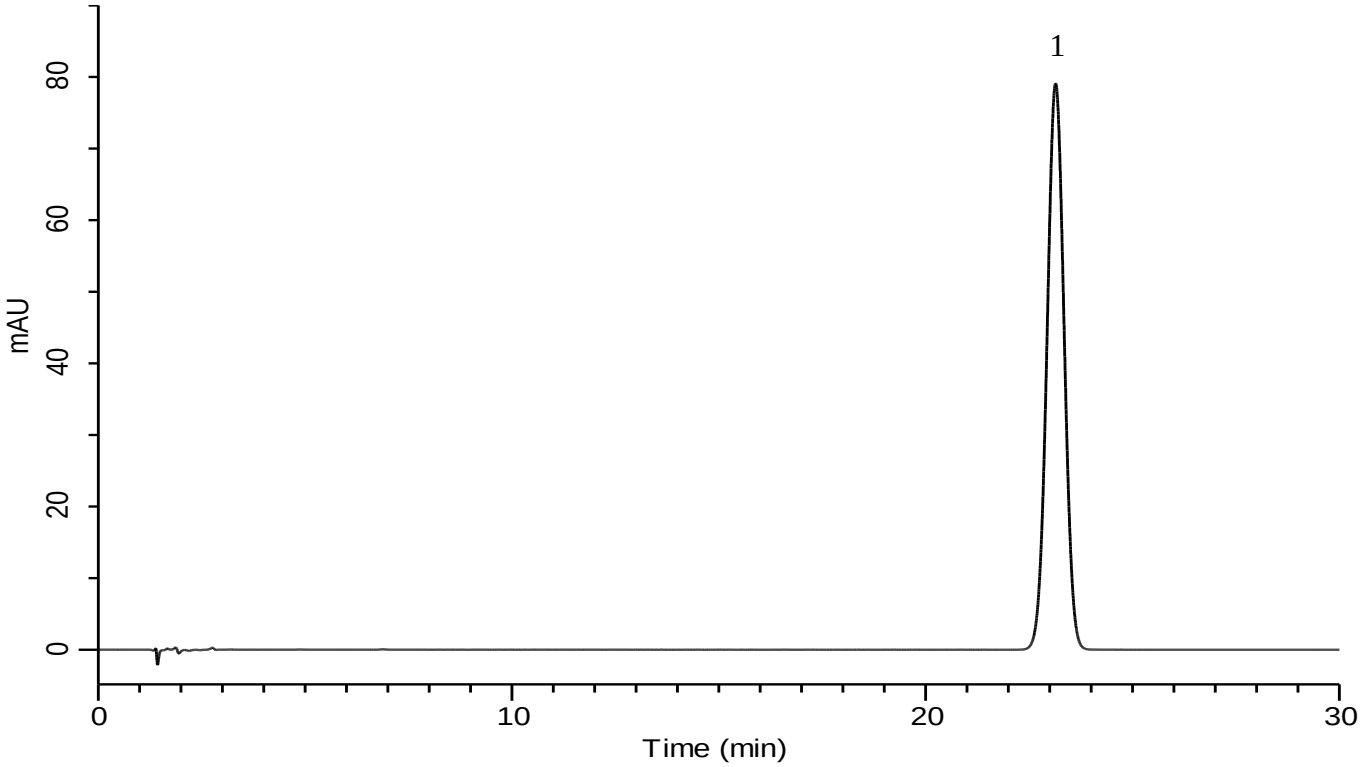
Analysis of Mirtazapine

(Under the Condition of USP41-NF36, Mirtazapine)

Standard solution of Assay



Conditions

System : GL7700 HPLC system
Column : InertSustain C18 (5 μm, 250 x 4.6 mm I.D.)
Column Cat. No. : 5020-07346
Eluent : CH_3CN/CH_3OH/THF/Buffer* = 15/12.5/7.5/65, v/v
Flow rate : 1.5 mL/min
Col. Temp. : 40 ℃
Detection : UV 290 nm (UV7750 UV Detector)
Injection Vol. : 10 μL
Sample : Standard

Analyte:

1. Mirtazapine 300 mg/L

Theoretical plates (1) : 14,327 (> 7,000)
Symmetry factor (1) : 1.01 (< 2.0)
RSD of the peak area of 1 (%)(n=6) : 0.05 (< 1.0)

* Dissolve 18 g of tetramethylammonium hydroxide pentahydrate in 950 mL of water. Adjust with phosphoric acid to a pH of 7.4. Dilute with water to 1 L.