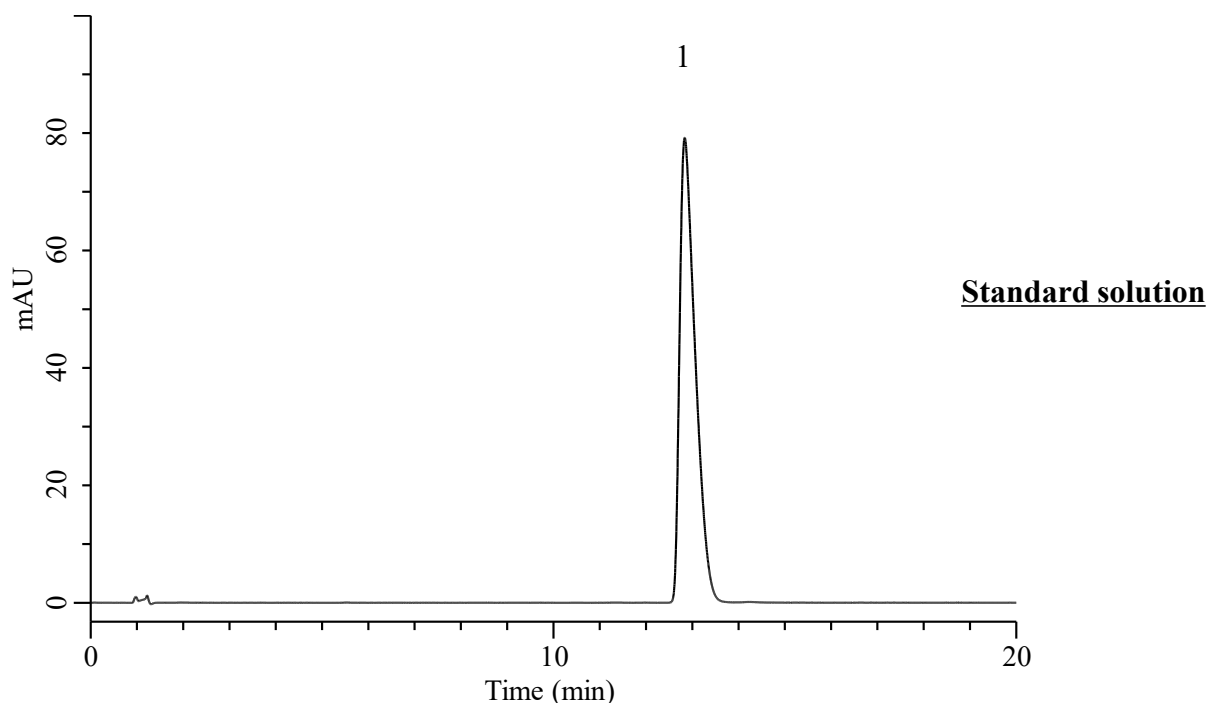


Analysis of Risperidone

(Under the Condition of Japanese Pharmacopoeia 19th,
Risperidone Tablets, Risperidone Fine Granules, Assay)



Conditions

System : Chromaster PLUS (HITACHI)
Column : Inertsil Hybrid-C18 (GL Sciences Inc.)
 (3.5 μ m, 150 x 3.0 mm I.D.)
Column Cat. No. : 5020-76036
Eluent : Solution*
Flow Rate : 0.80 mL/min
Col. Temp. : 25 °C
Detection : UV 275 nm (Chromaster 5420 UV-VIS)
Injection Vol. : 10 μ L
Sample : Standard in (0.1mol/L in H₂O/CH₃OH=3/2, v/v)

Analyte:

1. Risperidone 100 μ g/mL
 Theoretical plates number : 6838 (\geq 4000)
 Tailing factor : 1.82 (\leq 2.5)
 RSD of
 the peak area (%)(n=6) : 0.17 (\leq 1.0)

*: To 1000 mL of a mixture of water and acetonitrile (4:1) add 1.5 mL of trifluoroacetic acid, and adjust to pH 3.0 with ammonia solution (28).