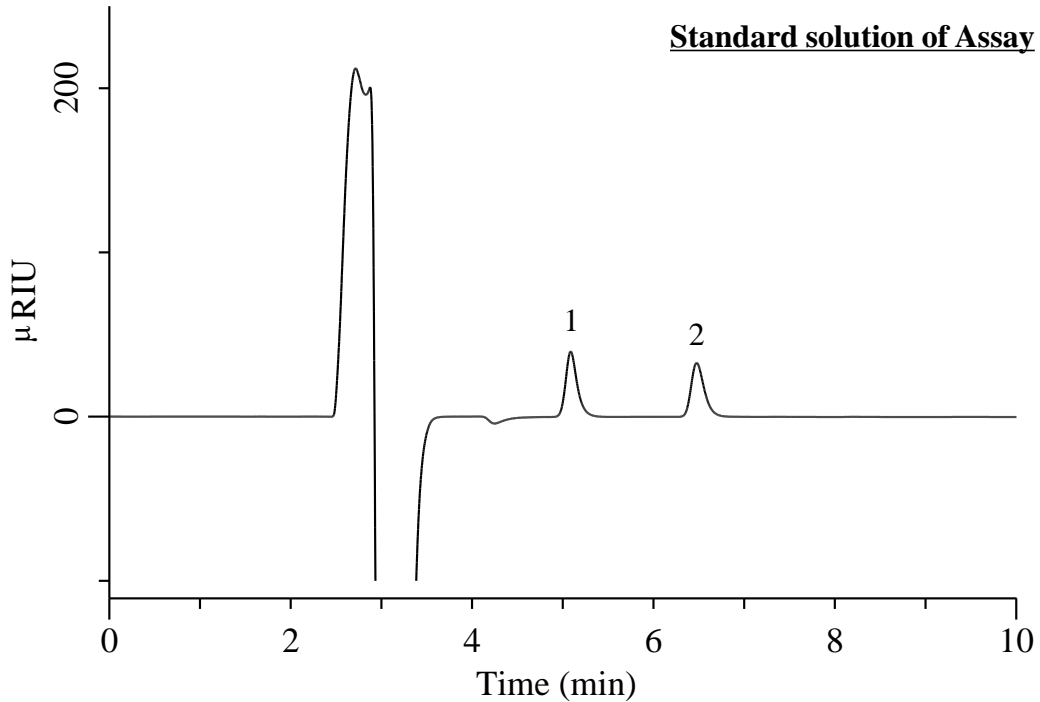


Analysis of Ursodiol

(Under the Condition of USP43-NF38, Ursodiol)



Conditions

System : Chromaster HPLC system (HITACHI)
Column : Inertsil WP300 C18 (GL Sciences Inc.)
 (5 μ m, 300 x 3.9 mm I.D.)
Column Cat. No. : 5020-90811
Eluent : A) CH₃CN
 B) H₂O
 A/B = 55/45, v/v
 (pH 3.0, 0.6 M H₃PO₄)
Flow Rate : 1.0 mL/min
Col. Temp. : 40 °C
Detection : RI
Injection Vol. : 50 μ L
Sample : Standard

Analyte:

1. Ursodiol 0.4 mg/mL
 2. Epiandrosterone 0.4 mg/mL

Resolution (1,2) : 5.8 (\geq 3.8)

RSD of the
 peak area of 1 (%) (n=6) : 0.19 (\leq 1.0)
 peak area of 2 (%) (n=6) : 0.20 (\leq 1.0)

Relative retention times
 Ursodiol : 5.09/6.48 (0.79)
 Epiandrosterone : 6.48/6.48 (1.0)