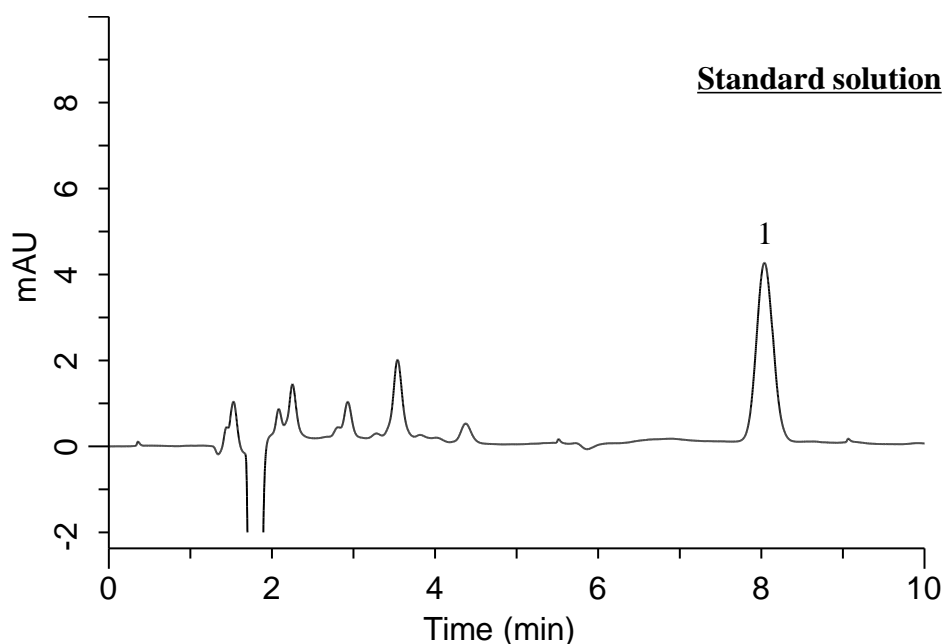


Analysis of Tranexamic acid

(Under the Condition of the Japanese Pharmacopoeia, Tranexamic acid Capsules)



Conditions

System : GL7700 HPLC system
Column : Inertsil ODS-4
 (5 μ m, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020-03945
Eluent : A) CH₃OH
 B) Buffer*
 A/B = 40/60, v/v
Flow Rate : 0.9 mL/min
Col. Temp. : 25 °C
Detection : UV 220 nm (PD7752 PDA Detector)
Injection Vol. : 10 μ L
Sample : Standard

Analyte:

1. Tranexamic acid 280 mg/L

Theoretical plate number : 6,899 (\geq 4,000)
 Tailing factor : 1.07 (\leq 2.0)
 RSD of the peak area (%) (n=6) : 0.25 (\leq 2.0)

*Dissolve 11.0 g of anhydrous sodium dihydrogen phosphate in 500 mL of water, and add 10 mL of triethylamine and 1.4 g of sodium lauryl sulfate. Adjust pH 2.5 with phosphoric acid, add water to make 600 mL.

【NOTE】

- 1) Fully equilibrate the column prior to the analysis. Fully equilibrate the column with eluent for at least 24 hrs at 1 mL/min.
- 2) Prepare the eluent at time of use, otherwise the retention time may shift.