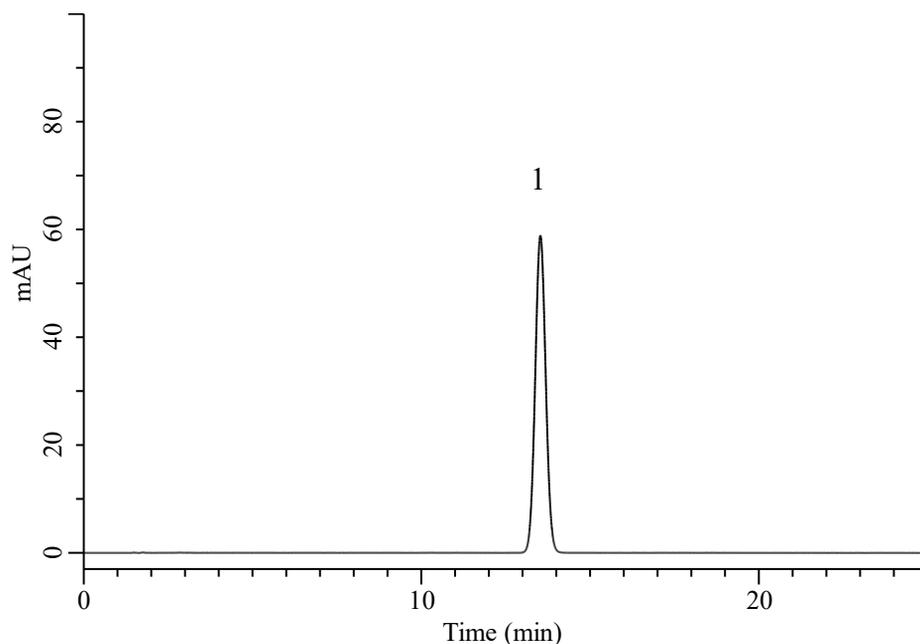


Analysis of Edoxaban tosylate

(Under the Condition of draft for USP, Edoxaban Tosylate , ASSAY)



Standard solution

Conditions

System : Primaide (HITACHI)
Column : Inertsil ODS-3 (GL Sciences Inc.)
 (5 μ m, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020-01731
Eluent : A) CH₃CN/Buffer* = 70/30 , v/v
 B) CH₃CN/Buffer* = 10/90 , v/v
 A/B = 32/68 , v/v
Flow Rate : 1.1 mL/min
Col. Temp. : 40 °C
Autosampler : 10 °C
Detection : UV 290 nm (Primaide 1410 UV)
Injection Vol. : 10 μ L
Sample : Standard in (CH₃CN/H₂O = 50/50, v/v)

Analyte:

1. Edoxaban tosylate 0.08 mg/mL

Tailing factor : (0.8 \leq) 1.04 (\leq 1.2)

RSD of the peak area of 1 (%) (n=6) : 0.11 (\leq 0.73)

*: 2.72 g/L of potassium phosphate, monobasic in water. Adjust with a solution of 2.84 g/L of sodium phosphate, dibasic, anhydrous in water to a pH of 7.0.