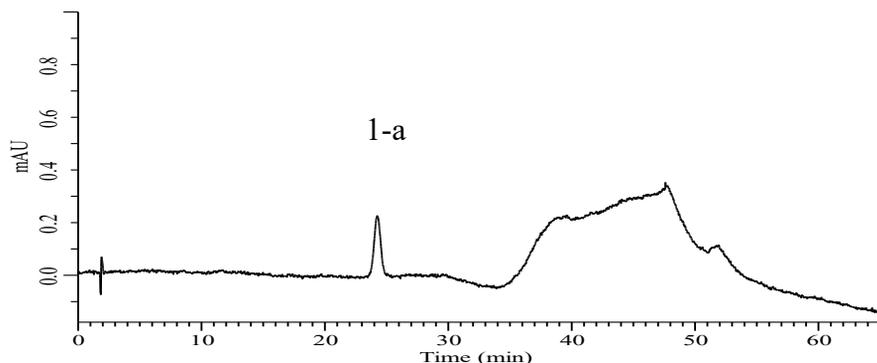
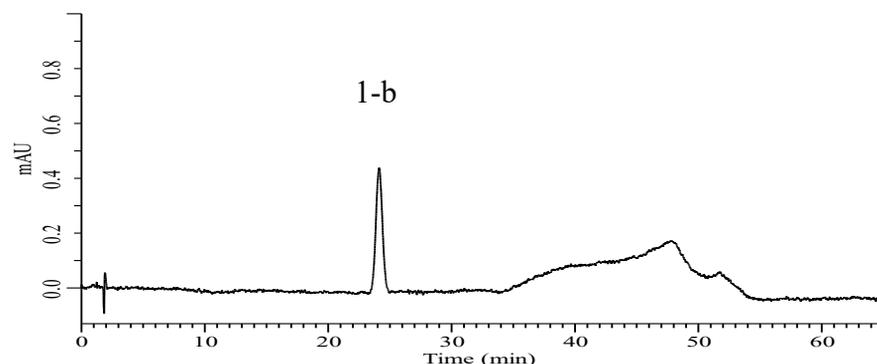


Analysis of Edoxaban tosylate

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



Sensitivity solution



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

Analyte:

1-a. Edoxaban tosylate 0.5 μ g/mL
 1-b. Edoxaban tosylate 1 μ g/mL

Signal-to-noise ratio (1-a) : 37.8 (≥ 10)

RSD of
 the peak area of 1-b (%) (n=6) : 1.25 (≤ 5.0)

Time (min)	A (vol %)	B (vol %)
0.0	27	73
30.0	27	73
45.0	80	20
50.0	27	73
65.0	27	73

Flow Rate : 1.05 mL/min
Col. Temp. : 40 $^{\circ}$ C
Autosampler : 10 $^{\circ}$ C
Detection : UV 290 nm (Primaide 1410 UV)
Injection Vol. : 10 μ L
Sample : Standard in (CH₃CN/H₂O=50/50, v/v)

*: 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.