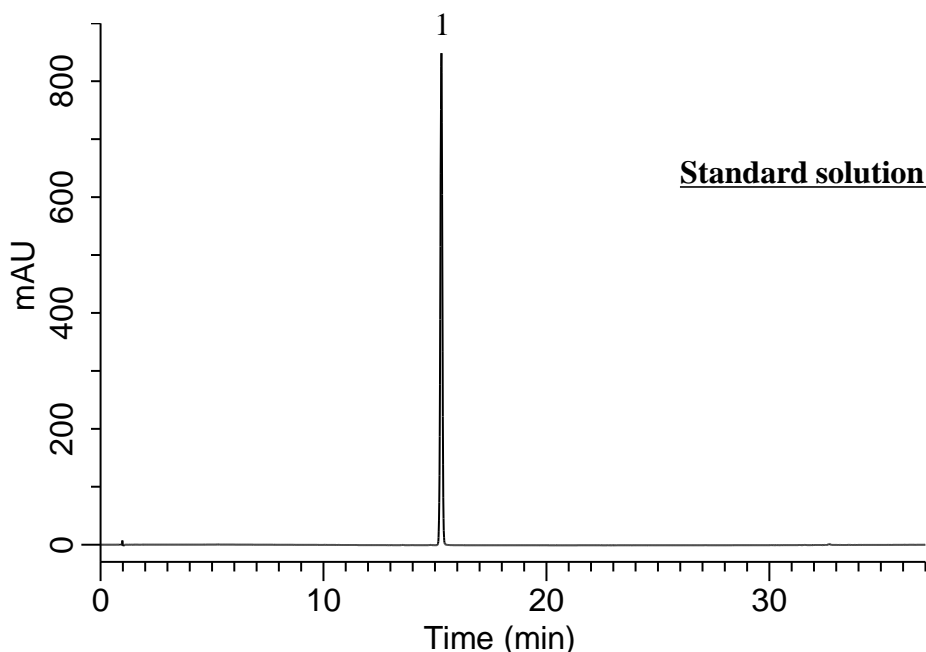


Analysis of Rivaroxaban

(Under the Condition of draft for USP)



Conditions

System : GL7700 HPLC system
Column : InertSustainSwift C18
 (3.5 μ m, 150 x 3.0 mm I.D.)
Column Cat. No. : 5020-
Eluent : A) CH₃CN
 B) CH₃OH/Buffer* = 5/95, v/v

Time (min)	A (vol%)	B (vol%)
0.0	2	98
2.0	2	98
8.0	16	84
25.0	36	64
37.0	80	20
37.1	2	98
50.0	2	98

Flow rate : 1.0 mL/min
Col. Temp. : 60 °C
Detection : UV 250 nm (PD7752 PDA Detector)
Injection Vol. : 3 μ L
Sample : Standard

Analyte:

1. Rivaroxaban 500 mg/L

Symmetry factor : 0.96 (\leq 2.0)
 RSD of the peak area (%)(n=6) : 0.19 (\leq 0.73)

【NOTE】

Operating pressure often exceeds 20 MPa.
 In that case, the column will not be immediately unavailable, but its lifetime may be a little shorter.

* Dissolve 1.36 g of potassium dihydrogen phosphate, 1 g of sodium hexanesulfonate, and 200 μ L of phosphoric acid in water. Dilute with water to 1 L.