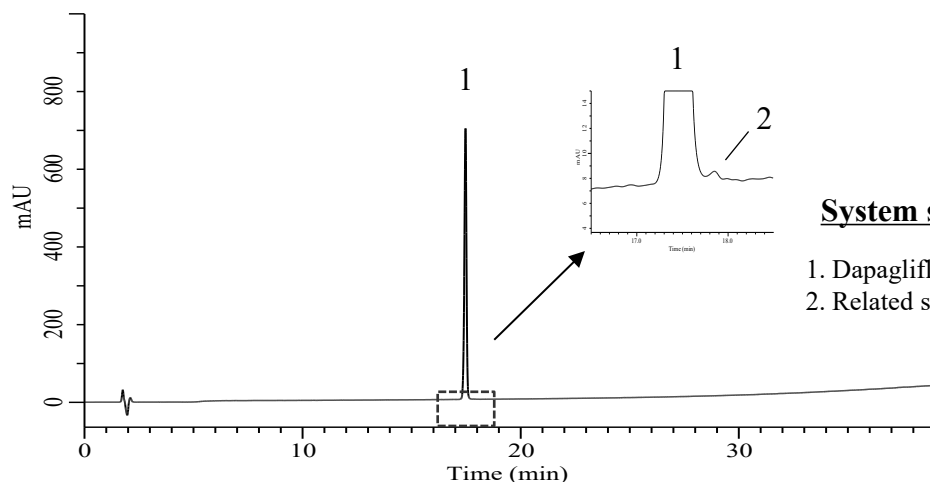


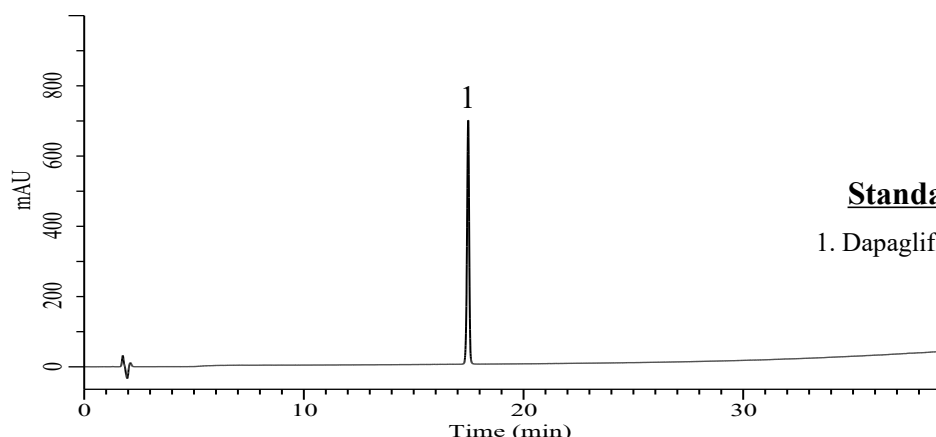
Analysis of Dapagliflozin propanediol

(Under the Condition of the draft for JP, Dapagliflozin Propylene Glycolate Hydrate)



System suitability solution

1. Dapagliflozin propanediol 0.2 mg/mL
2. Related substances A 0.16 μ g/mL



Standard solution of Assay

1. Dapagliflozin propanediol 0.2 mg/mL

Conditions

System : Chromaster PLUS HPLC system (HITACHI)
Column : InertSustain C18 (GL Sciences Inc.)
 (3.5 μ m, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020-89996
Eluent : A) TFA/CH₃CN = 1/2000, v/v
 B) TFA/H₂O = 1/2000, v/v

Time (min)	A (vol %)	B (vol %)
0	15	85
2	15	85
36	90	10
39	90	10

Flow Rate : 1.0 mL/min
Col. Temp. : 30 $^{\circ}$ C
Detection : UV 220 nm
Injection Vol. : 10 μ L
Sample : Standard

Analyte:

1. Dapagliflozin propanediol
2. Related substances A

Tailing factor
 peak of 1 : 0.94 (0.8 - 1.5)

Resolution : 2.38 ($\geq$ 2.0)

Relative retention times
 Dapagliflozin propanediol : 17.467 (1.00)
 Related substances A : 17.853 (1.02)

RSD of the peak area (%) (n=6) : 0.08 ($\leq$ 0.85)