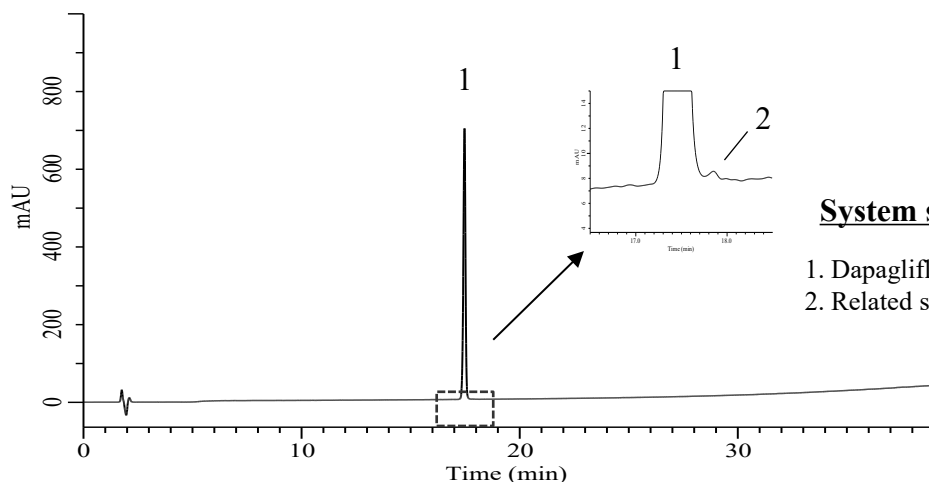


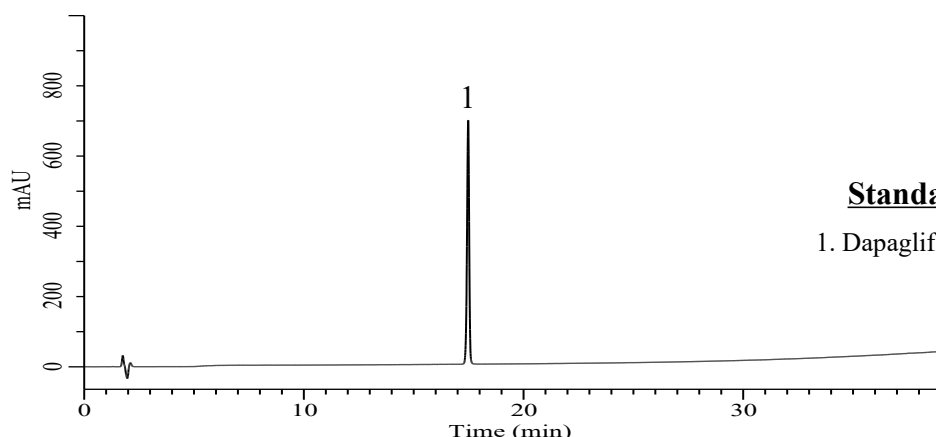
Analysis of Dapagliflozin propanediol

(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 °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)