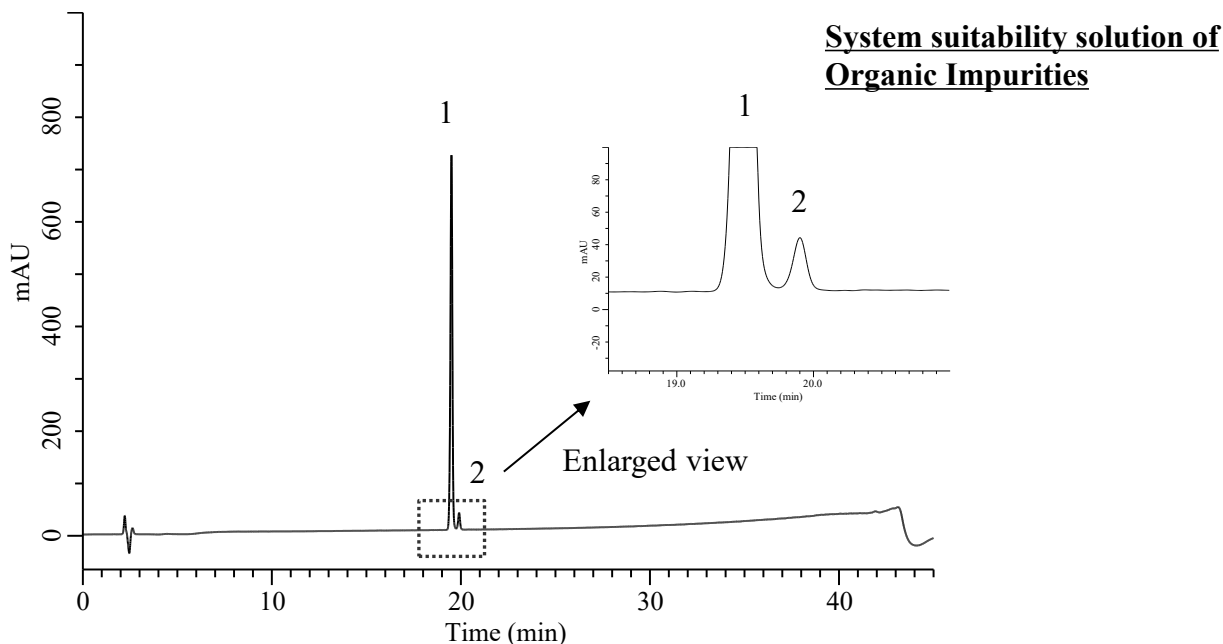


Analysis of Dapagliflozin propanediol

(Under the Condition of the USP-NF, Dapagliflozin Propanediol)



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 = 0.5/1000, v/v
 B) TFA/H₂O = 0.5/1000, v/v

Analyte:

1. Dapagliflozin propanediol 0.2 mg/mL
 2. Dapagliflozin related compound A 0.007 mg/mL

Resolution : 2.15 (≥ 2.0)

Tailing factor : 0.94 (0.8 - 1.5)

Relative retention times

1. Dapagliflozin propanediol : 19.493 (1.00)
 2. Dapagliflozin related compound A : 19.900 (1.24)

Time (min)	A (vol %)	B (vol %)
0	15	85
2	15	85
36	90	10
39	90	10
40	15	85
45	15	85

Flow Rate : 1.0 mL/min
Col. Temp. : 30 °C
Detection : UV 220 nm (5430 DAD)
Injection Vol. : 10 μ L
Sample : Standard