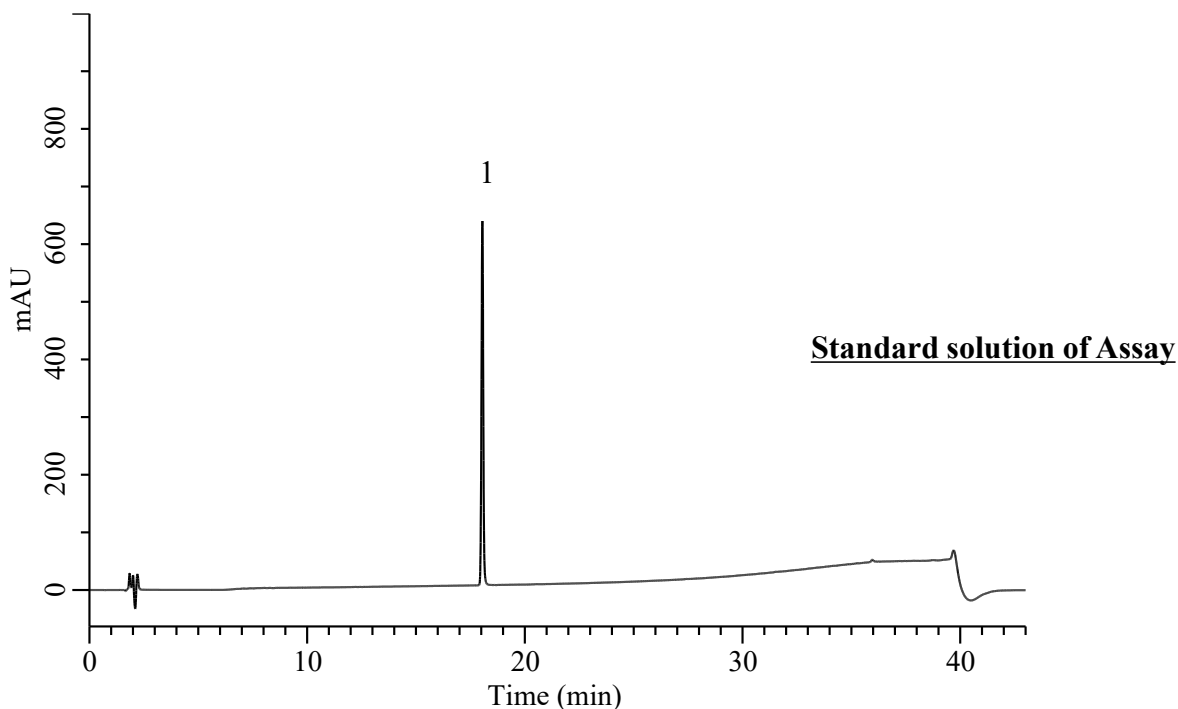


Analysis of Dapagliflozin propanediol

(Under the Condition of the draft for USP, Dapagliflozin Tablets)



Conditions

System : Cromaster PLUS HPLC system (HITACHI)
Column : InertSustain C18 (GL Sciences Inc.)
 (3 μ m, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020-07445
Eluent : A) TFA/CH₃CN = 0.5/1000, v/v
 B) TFA/H₂O = 0.5/1000, v/v

Analyte:
 1. Dapagliflozin propanediol 0.1 mg/mL

Tailing factor : 1.03 (0.8 - 1.5)

RSD of the peak area (%)(n=6) : 0.79 (\leq 1.0)

Time (min)	A (vol %)	B (vol %)
0	10	90
3	10	90
33	95	5
36	95	5
37	10	90
43	10	90

Flow Rate : 1.0 mL/min
Col. Temp. : 35 °C
Detection : UV 220 nm (5430 DAD)
Injection Vol. : 15 μ L
Sample : Standard