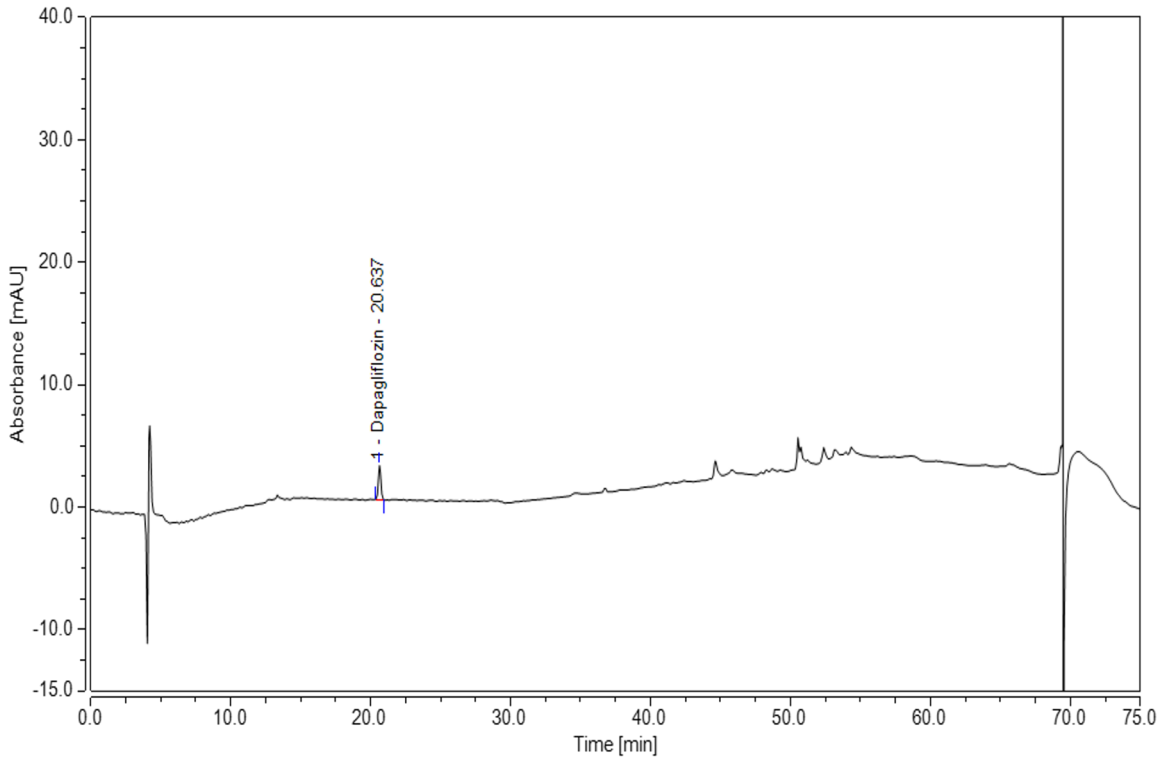




Dapagliflozin Related Substance USP On Endurus[®] C18 (Classic) HPLC Column



Test Condition

(As US Pharmacopeia)

Column: Endurus[®] C18 Classic 250x4.6 mm, 5µm

Injection: 20 µL

Detection: UV 225 nm

Flow Rate: 0.8 mL/min

Mobile Phase: A: Add 1 ml of orthophosphoric acid in 1 L of water. Pass through 0.45-µm or finer porosity membrane filter.

B: Acetonitrile

Gradient: See Table

Diluent: Degassed mixture of water and acetonitrile in the ratio of 50:50 v/v

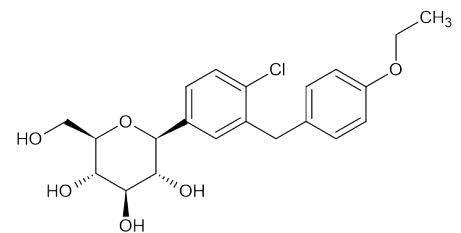
Temperature: Ambient temperature for column
Autosampler temperature: 8°C

Sample preparation: Dissolve 4.0 mg of Dapagliflozin sample into 10 ml volumetric flask, add 5 ml diluent and sonicate to dissolve, make up to volume with diluent.

Standard solution: 0.0006 mg /ml concentration of solution using Dapagliflozin in diluent.

Pressure Drop: 40-115 Bar (580-1668 psi)

Time (Min)	%A	%B
0.01	80	20
10	60	40
25	60	40
35	40	60
50	2	98
65	2	98
67	80	20
75	80	20



Chromatographic data

No.	Compound	Retention Time (min)	Tailing Factor
1	Dapagliflozin	20.637	1.07

Parameter	USP Specification	Observed Value
Tailing Factor of Dapagliflozin USP requirements	0.8 - 1.5	1.07

