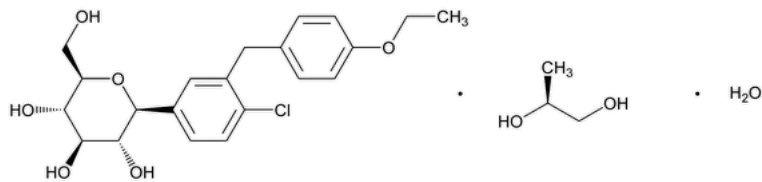


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Add the following:

▲Dapagliflozin Propanediol



$C_{21}H_{25}ClO_6 \cdot C_3H_8O_2 \cdot H_2O$ 502.99
D-Glucitol, 1,5-anhydro-1-C-[4-chloro-3-[(4-ethoxyphenyl)methyl]phenyl]-, (1S)-, compd. with (2S)-1,2-propanediol, hydrate (1:1:1);
(1S)-1,5-Anhydro-1-C-[4-chloro-3-[(4-ethoxyphenyl)methyl]phenyl]-D-glucitol (S)-propane-1,2-diol (1:1) monohydrate;
(2S,3R,4R,5S,6R)-2-[4-Chloro-3-(4-ethoxybenzyl)phenyl]-6-(hydroxymethyl)tetrahydro-2H-pyran-3,4,5-triol (S)-propane-1,2-diol (1:1)
monohydrate CAS RN®: 960404-48-2; UNII: 887K2391VH.

DEFINITION

Dapagliflozin Propanediol contains NLT 98.0% and NMT 102.0% of dapagliflozin ($C_{21}H_{25}ClO_6$) calculated on the anhydrous, propanediol-free, and solvent-free basis.

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS.** (197), *Infrared Spectroscopy*: 197A or 197K
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Solution A: [Trifluoroacetic acid](#) and [water](#) (0.5: 1000)
Solution B: [Trifluoroacetic acid](#) and [acetonitrile](#) (0.5: 1000)
Mobile phase: See [Table 1](#).

Table 1

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

Standard solution: 0.2 mg/mL of [USP Dapagliflozin Propanediol RS](#) in [acetonitrile](#)

Sample solution: 0.2 mg/mL of Dapagliflozin Propanediol in [acetonitrile](#)

Chromatographic system

(See [Chromatography \(621\), System Suitability.](#))

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 15-cm; 3.5-µm packing [L1](#)

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: 0.8–1.5

Relative standard deviation: NMT 0.85% for 6 injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of dapagliflozin ($C_{21}H_{25}ClO_6$) in the portion of Dapagliflozin Propanediol taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of dapagliflozin from the *Sample solution*

r_S = peak response of dapagliflozin from the *Standard solution*

C_S = concentration of [USP Dapagliflozin Propanediol RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Dapagliflozin Propanediol in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the anhydrous, propanediol-free, and solvent-free basis

OTHER COMPONENTS

• **CONTENT OF PROPANEDIOL**

Internal standard solution: 2.64 mg/mL of [USP Ethylene Glycol RS](#) in [dimethylacetamide](#)

Standard solution: 3.0 mg/mL of [USP Propylene Glycol RS](#) in *Internal standard solution*

Sample solution: 20 mg/mL of Dapagliflozin Propanediol in *Internal standard solution*

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: GC

Detector: Flame ionization

Column: 0.32-mm × 15-m fused silica; coated with a 0.5-µm film of phase [G14](#). [NOTE—Phases of [G15](#), [G16](#), [G20](#), or [G39](#) may also be suitable for use.]

Temperatures

Injection port: 240°

Detector: 240°

Column: See [Table 2](#).

Table 2

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
150	—	150	2
150	40	240	4

Carrier gas: Helium

Flow rate: 3.5 mL/min

Injection volume: 1.0 µL

Injection type: Split, split flow 80.8 mL/min

Run time: NLT 5 times the retention time of propanediol

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for propanediol and ethylene glycol are 1.0 and 1.1, respectively.]

Suitability requirements

Resolution: NLT 1.5 between propanediol and ethylene glycol

Relative standard deviation: NMT 3.0% for propanediol and ethylene glycol

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of propanediol in the portion of Dapagliflozin Propanediol taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$