



Product Name:	Dapagliflozin Propandiol Monohydrate		
Batch No:	21600-102L301-101-MC	Molecular Formula:	C ₂₄ H ₃₅ ClO ₉ ·
CAS No:	960404-48-2	Molecular Weight:	502.98 g/mol
Mfg. Date:	Aug, 2024	Date of Analysis:	Aug, 2024
Analysis No:	QC-DGN-03002	Retest Date:	Aug, 2026

Tests	Standard	Result
Appearance	White or off-white solid powder	Conform
Solubility	Freely soluble in ethanol, soluble in acetonitrile and Slightly soluble in water	Conform
Identification (IR)	Complies with standard	Conform
Identification (HPLC)	The retention time of the main peak of the sample solution corresponds to that of standard solution	Conform
Specific Optical Rotation	+13° to 17°	+13.31 °
Water Determination(KF)	3.5-4.5 %	3.77 %
Residue on ignition	Not more than 0.1 %	0.03 %
Heavy metals	Not more than 20 ppm	Conform
Related Substances	Each unknown Impurity ≤ 0.1 %	0.015 %
	Total Impurities ≤ 1.0 %	0.17 %
Assay (Based on Anhydrous substance)	98.0-102.0 %	99.19 %
Propandiol determination	13.5-17.0 %	16.91 %
Residual Solvents	Methanol ≤ 3000 ppm	Not Detected
	Ethanol ≤ 5000 ppm	Not Detected
	Acetonitrile ≤ 410 ppm	Not Detected
	Dichloromethane ≤ 600 ppm	Not Detected
	Ethyl acetate ≤ 5000 ppm	72 ppm
	Tetrahydrofuran ≤ 720 ppm	Not Detected
	n-Hexane ≤ 290 ppm	Not Detected
	Toluene ≤ 890 ppm	Not Detected
	N-Heptane ≤ 5000 ppm	1140 ppm

Final Result	According To: In House Monograph	☒ Approved	☐ Rejected
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Comment:
- Particle size distribution: D90 ≤ 8.3 μm - Storage: Preserve in well-closed, light-resistant containers. Store at controlled room temperature

QC Manager: Dr.Beheshti	TODA CO.	Date: Oct 30, 2024
Authorized Person: Dr.Akhlaghi	QC Department	Date: Oct 30, 2024