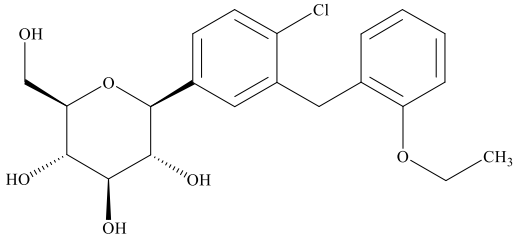


Certificate of Analysis

Certificate No.: 20201218018

Date: December 18, 2020

Retest date: December 9, 2023

Compound Name:	Dapagliflozin Impurity 8	
Synonyms:	(2S,3R,4R,5S,6R)-2-(4-chloro-3-(2-ethoxybenzyl)phenyl)-6-(hydroxymethyl)tetrahydro-2H-pyran-3,4,5-triol	
TLC Catalogue Number:	D-6212	
CAS Number:	2040305-05-1	
Molecular Weight:	408.88	
Molecular Formula:	C ₂₁ H ₂₅ ClO ₆	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	4047-094A6	
Storage Conditions:	Store at 2-8 °C	
Solubility:	Methanol, DMSO	

Test Description	Specifications	Results
Visual Description	White to off-white solid	Conforms
Identification		
IR	Conforms to structure	Conforms
MS	Conforms to structure	Conforms
¹H NMR	Conforms to structure	Conforms
Elemental Analysis	Conforms to structure	Conforms
Purity (HPLC)	Not less than 95.0%	99.5%
Impurity (HPLC)	RT 9.73, 0.12%; RT 10.09, 0.14%	
Water Content (KF)	N/A	2.0%
Optical Rotation	N/A	$[\alpha]_D^{25.0}(c=0.42, \text{CHCl}_3): +10.4^\circ$
Residual Solvents (NMR)	0.1% <i>n</i> -hexane	
Assay (%)	Not less than 90.0%	97.4%
Recommendation:	Released.	

Name	Department	Signature	Date
Reviewed and approved by:	Analytical Services		
Approved by:	Quality Assurance		

Attachments: HPLC, IR, MS and NMR spectra.