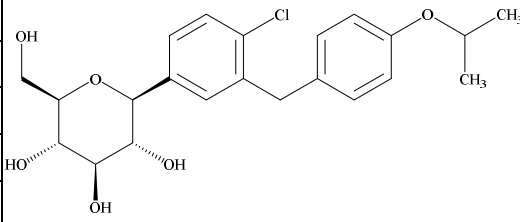


Certificate of Analysis

 Certificate No.: **20200318020**

Date: March 18, 2020

Retest date: March 14, 2023

Compound Name:	Dapagliflozin Impurity 44	
Synonyms:	(2S,3R,4R,5S,6R)-2-(4-chloro-3-(4-isopropoxybenzyl)phenyl)-6-(hydroxymethyl)tetrahydro-2H-pyran-3,4,5-triol	
TLC Catalogue Number:	D-6252	
CAS Number:	946525-39-9	
Molecular Weight:	422.90	
Molecular Formula:	C ₂₂ H ₂₇ ClO ₆	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	3825-035A4	
Storage Conditions:	Store at 2-8 °C	
Solubility:	Methanol, DMSO, DMF, Acetonitrile	

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
Purity (HPLC)	Not less than 95.0%	98.6%
Impurity (HPLC)	RT 13.68, 0.17%; RT 14.11, 0.64%; RT 14.46, 0.47%	
Water Content (KF)	N/A	0.3%
Optical Rotation	N/A	$[\alpha]_D^{25.0}(c=0.56, \text{CH}_3\text{OH}): +14.4^\circ$
Residual Solvents (NMR)	0.5% methanol	
Assay (%)	Not less than 90.0%	97.8%
Recommendation:	Released.	

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

Attachments: HPLC, IR, MS and NMR spectra.