

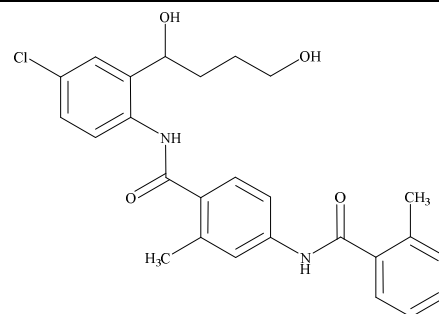
Certificate of Analysis

Certificate No.: 20190306015

Date: March 6, 2019

Retest date: March 6, 2022

Compound Name: Tolvaptan Impurity 3 (DM-4104)	
Synonyms:	<i>N</i> -(4-Chloro-2-(1,4-dihydroxybutyl)phenyl)-2-methyl-4-(2-methylbenzamido)benzamide
TLC Catalogue Number:	T-693
CAS Number:	1587638-01-4
Molecular Weight:	466.96
Molecular Formula:	C ₂₆ H ₂₇ ClN ₂ O ₄
Source:	TLC Pharmaceutical Standards
Source Lot No.:	2443-022A3
Storage Conditions:	Store at 2-8 °C.
Solubility:	DMSO, Solution of Methanol and Acetonitrile



Test Description	Specifications	Results
Visual Description	White to off-white solid	Conforms
Identification		
IR	Conforms to structure	Conforms
MS	Conforms to structure	Conforms
¹ H NMR	Conforms to structure	Conforms
Purity (HPLC)	Not less than 95.0%	98.8%
Impurity (HPLC)	RT 12.78, 0.91%; RT 14.61, 0.17%	
Water Content (KF)	N/A	0.2%
Residual Solvents (NMR)	0.7% methanol and 0.1% dichloromethane	
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.