

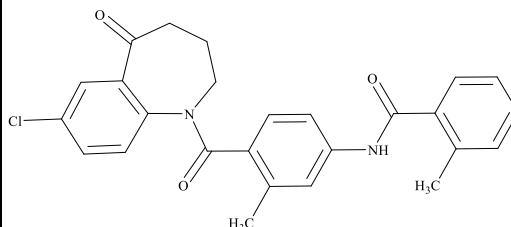
Certificate of Analysis

Certificate No.: 20210906013

Date: September 6, 2021

Retest date: September 1, 2024

Compound Name: Tolvaptan Impurity 5 (DM-21826)	
Synonyms:	<i>N</i> -(4-(7-chloro-5-oxo-2,3,4,5-tetrahydro-1 <i>H</i> -benzo[<i>b</i>]azepine-1-carbonyl)-3-methylphenyl)-2-methylbenzamide
TLC Catalogue Number:	T-696
CAS Number:	137973-76-3
Molecular Weight:	446.93
Molecular Formula:	C ₂₆ H ₂₃ ClN ₂ O ₃
Source:	TLC Pharmaceutical Standards
Source Lot No.:	2637-059A3
Storage Conditions:	Store at 2-8 °C
Solubility:	DMSO, 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%	98.7%
Impurity (HPLC)	RT 11.49, 0.30%; RT 15.37, 0.57%	
Water Content (KF)	N/A	1.9%
Residual Solvents (NMR)	No residual solvent	
Assay (%)	Not less than 90.0%	96.8%
Recommendation:	Release.	

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

Attachments: HPLC, IR, MS and NMR spectra.