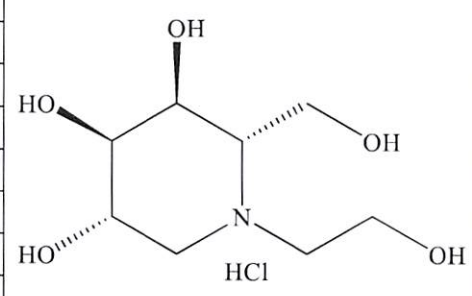


Certificate of Analysis

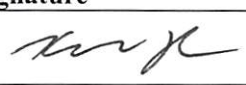
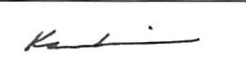
Certificate No.: **20260624009**

Date: June 24, 2026

Retest date: June 23, 2029

Compound Name:	Miglitol Impurity 4 HCl		
Synonyms:	(2S,3S,4R,5S)-1-(2-hydroxyethyl)-2-(hydroxymethyl)piperidine-3,4,5-triol, hydrochloride (1:1)		
TLC Catalogue Number:	M-646		
CAS Number:	N/A		
Alternate CAS Number:	1550201-56-3 (free base)		
Molecular Weight:	207.23 36.46		
Molecular Formula:	C ₈ H ₁₇ NO ₅ · HCl		
Source:	TLC Pharmaceutical Standards		
Source Lot No.:	7506-012A3		
Storage Conditions:	Hygroscopic, store at 2-8 °C		
Solubility:	Methanol, DMSO, DMF, Water		

Test Description	Specifications	Results
Visual Description	Brown semi-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%	100.0%
Impurity (HPLC)	N/A	
Water Content (KF)	N/A	0.7%
Optical Rotation	N/A	[α] _D ^{25.0} (c=0.98, H ₂ O): +6.9°
Residual Solvents (NMR)	0.3% methanol	
Assay (%)	Not less than 90.0%	99.0%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		06/24/2026
Approved by:	Quality Assurance		06/24/2026

Attachments: Peak Attribution Table, Assay Calculation, HPLC, IR, MS and NMR spectra.