

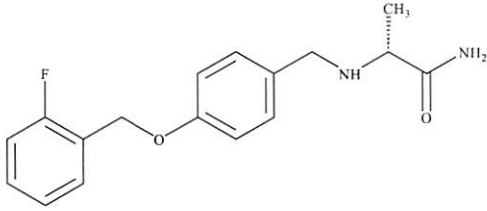
Certificate of Analysis

Certificate No.: **20250528003**



Date: May 28, 2025

Retest date: May 22, 2028

Compound Name: <i>ent</i> -Safinamide Impurity 16	
Synonyms:	(R)-2-((4-((2-fluorobenzyl)oxy)benzyl)amino)propanamide
TLC Catalogue Number:	S-073004
CAS Number:	878379-14-7
Alternate CAS Number:	1160513-64-3 (Methanesulfonate salt)
Molecular Weight:	302.35
Molecular Formula:	C ₁₇ H ₁₉ FN ₂ O ₂
Source:	TLC Pharmaceutical Standards
Source Lot No.:	6822-035A2
Storage Conditions:	Store at 2-8 °C
Solubility:	Methanol, DMSO, Acetonitrile, Ethanol



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%	99.4%
Impurity (HPLC)	RT 8.27, 0.26%; RT 11.73, 0.21%	
Purity (Chiral HPLC)	Not less than 98.0%	99.7%
Water Content (KF)	N/A	0.2%
Optical Rotation	N/A	[α] _D ^{25.0} (c=0.72, CH ₃ OH): +9.7°
Residual Solvents (NMR)	No residual solvent	
Assay (%)	Not less than 90.0%	98.9%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		05/28/2025
Approved by:	Quality Assurance		05/28/2025

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