

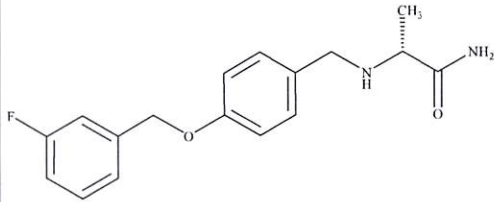
Certificate of Analysis

Certificate No.: **20250102025**



Date: January 2, 2025

Retest date: December 31, 2027

Compound Name: Safinamide Impurity 4	
Synonyms:	(R)-2-((4-((3-fluorobenzyl)oxy)benzyl)amino)propanamide
TLC Catalogue Number:	S-073006
CAS Number:	174756-44-6
Molecular Weight:	302.35
Molecular Formula:	C ₁₇ H ₁₉ FN ₂ O ₂
Source:	TLC Pharmaceutical Standards
Source Lot No.:	2147-013A1
Storage Conditions:	Store at 2-8 °C
Solubility:	Methanol, DMSO



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%	99.6%
Impurity (HPLC)	RT 3.98, 0.16%; RT 4.20, 0.23%	
Purity (Chiral HPLC)	Not less than 98.0%	99.8%
Water Content (KF)	N/A	0.1%
Optical Rotation	[α] _D ^{25.0} (c=2.00, CH ₃ OH): +10.6°	[α] _D ^{25.0} (c=1.58, CH ₃ OH): +9.6°
Residual Solvents (NMR)	0.1% ethyl acetate	
Assay (%)	Not less than 90.0%	99.2%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		01/07/2025
Approved by:	Quality Assurance		01/07/2025

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