

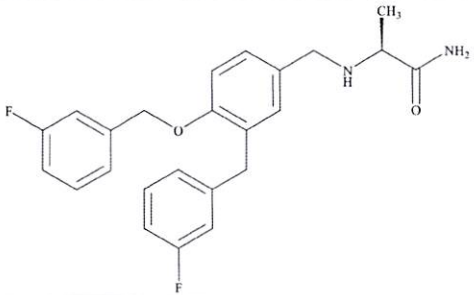


Certificate of Analysis



Certificate No.: 20240718013

Date: July 18, 2024

Retest date: July 17, 2027

Compound Name:	Safinamide Impurity 1	
Synonyms:	(S)-2-((3-(3-fluorobenzyl)-4-((3-fluorobenzyl)oxy)benzyl)amino)propanamide	
TLC Catalogue Number:	S-073002	
CAS Number:	1000370-27-3	
Molecular Weight:	410.46	
Molecular Formula:	C ₂₄ H ₂₄ F ₂ N ₂ O ₂	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	3207-079A6	
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
¹H NMR	Conforms to structure	Conforms
Purity (HPLC)	Not less than 95.0%	98.6%
Impurity (HPLC)	RT 4.19, 0.69%; RT 7.13, 0.75%	
Water Content (KF)	N/A	0.7%
Optical Rotation	N/A	$[\alpha]_D^{20.0}(c=0.47, CH_3OH): -7.8^\circ$
Residual Solvents (NMR)	0.9% isopropyl ether	
Assay (%)	Not less than 90.0%	97.0%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		07/19/2024
Approved by:	Quality Assurance		07/19/2024

Attachments: HPLC, IR, MS and NMR spectra.