

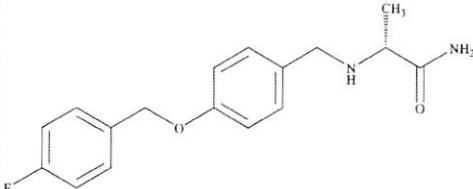


Certificate of Analysis


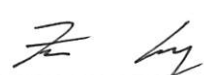
Certificate No.: 20240705033

Date: July 5, 2024

Retest date: July 2, 2027

Compound Name:	<i>ent</i> -Safinamide Impurity 17	
Synonyms:	(R)-2-((4-((4-fluorobenzyl)oxy)benzyl)amino)propanamide	
TLC Catalogue Number:	S-073031	
CAS Number:	2650285-53-1	
Molecular Weight:	302.35	
Molecular Formula:	C ₁₇ H ₁₉ FN ₂ O ₂	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	6303-039A3	
Storage Conditions:	Store at 2-8 °C	
Solubility:	Methanol, DMSO, 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%	99.9%
Impurity (HPLC)	RT 5.01, 0.10%	
Purity (Chiral HPLC)	Not less than 98.0%	99.6%
Water Content (KF)	N/A	0.2%
Optical Rotation	N/A	$[\alpha]_D^{22.0}(c=0.44, \text{CHCl}_3): -6.6^\circ$
Residual Solvents (NMR)	No residual solvent	
Assay (%)	Not less than 90.0%	99.3%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		07/08/2024
Approved by:	Quality Assurance		07/08/2024

Attachments: HPLC, IR, MS and NMR spectra.