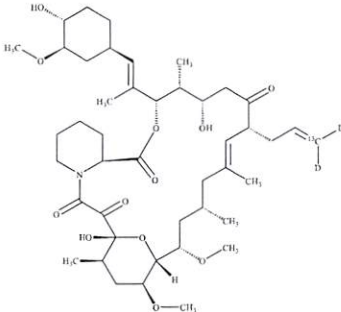


Certificate of Analysis


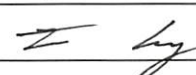
Certificate No.: 20251230031

Date: December 30, 2025

Retest date: December 29, 2028

Compound Name:	Tacrolimus- ¹³ C-d ₂	
Synonyms:	15,19-epoxy-3 <i>H</i> -pyrido[2,1- <i>c</i>][1,4]oxaazacyclotricosine-1,7,20,21 (4 <i>H</i> ,23 <i>H</i>)-tetrone,5,6,8,11,12,13,14,15,16,17,18,19,24,25,26,26a-hexadecahydro-5,19-dihydroxy-3-[(1 <i>E</i>)-2-[(1 <i>R</i> ,3 <i>R</i> ,4 <i>R</i>)-4-hydroxy-3-methoxycyclohexyl]-1-methylethenyl]-14,16-dimethoxy-4,10,12,18-tetramethyl-8-(2-propen-1-yl-3- ¹³ C-2,2-d ₂)-, (3 <i>S</i> ,4 <i>R</i> ,5 <i>S</i> ,8 <i>R</i> ,9 <i>E</i> ,12 <i>S</i> ,14 <i>S</i> ,15 <i>R</i> ,16 <i>S</i> ,18 <i>R</i> ,19 <i>R</i> ,26a <i>S</i>)	
TLC Catalogue Number:	T-392	
CAS Number:	1356841-89-8	
Alternate CAS Number:	104987-11-3 (non-labelled)	
Molecular Weight:	807.04	
Molecular Formula:	C ₄₃ ¹³ CH ₆₇ D ₂ NO ₁₂	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	7252-009A4	
Storage Conditions:	Store at 2-8 °C	
Solubility:	Methanol, DMSO, Acetonitrile	

Test Description	Specifications	Results
Visual Description	Pale yellow solid	Conforms
Identification IR MS ¹ H NMR	Conforms to structure Conforms to structure Conforms to structure	Conforms Conforms Conforms
Purity (HPLC)	Not less than 90.0%	91.9%
Impurity (HPLC)	RT 4.56, 1.06%; RT 7.66, 2.56%; RT 13.02, 1.52%	
Isotopic Enrichment	Not less than 98.0%	99.0% D; 99.0% ¹³C
Water Content (KF)	N/A	0.3%
Optical Rotation	N/A	[α]_D^{20.0}(c=0.43, CHCl₃): -82.6°
Residual Solvents (NMR)	3.5% acetone	
Assay (%)	Not less than 85.0%	88.4%
Recommendation:	Release. The compound contains 2.6% isomeric impurity (RT 7.66) according to its HPLC and LC-MS.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		01/06/2026
Approved by:	Quality Assurance		01/06/2026

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