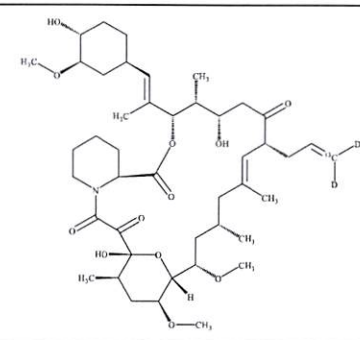


Certificate of Analysis


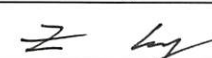
 Certificate No.: **20260402012**

Date: April 2, 2026

Retest date: March 26, 2029

Compound Name:	Tacrolimus-¹³C-d₂	
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- <i>d</i> 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> ,26 <i>aS</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.:	7382-014A3	
Storage Conditions:	Store at 2-8 °C	
Solubility:	Methanol, DMSO, Acetonitrile	

Test Description	Specifications	Results
Visual Description	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 90.0%	97.7%
Impurity (HPLC)	RT 8.21, 0.33%; RT 11.72, 0.97%; RT 13.44, 0.33%	
Isotopic Enrichment	Not less than 98.0%	99.0% D; 99.0% ¹³C
Water Content (KF)	N/A	0.5%
Optical Rotation	N/A	[α] _D ^{20.0} (c=0.53, CHCl ₃): -83.3°
Residual Solvents (NMR)	No residual solvent	
Assay (%)	Not less than 85.0%	97.2%
Recommendation:	Release. The compound contains 0.3% M+0 according to its LC-MS.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		04/02/2026
Approved by:	Quality Assurance		04/02/2026

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