



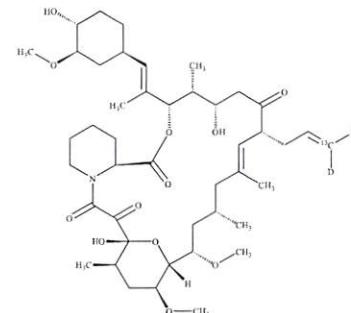
## Certificate of Analysis

Certificate No.: 20251230031

Date: December 30, 2025

Retest date: December 29, 2028

Compound Name:	Tacrolimus- <sup>13</sup> C-d <sub>2</sub>
Synonyms:	15,19-epoxy-3H-pyrido[2,1-c][1,4]oxaazacyclotricosine-1,7,20,21 (4H,23H)-tetrone,5,6,8,11,12,13,14,15,16,17,18,19,24,25,26,26a-hexadecahydro-5,19-dihydroxy-3-[(1E)-2-[(1R,3R,4R)-4-hydroxy-3-methoxycyclohexyl]-1-methylethyl]-14,16-dimethoxy-4,10,12,18-tetramethyl-8-(2-propen-1-yl-3- <sup>13</sup> C-2,2-d <sub>2</sub> )-, (3S,4R,5S,8R,9E,12S,14S, 15R,16S,18R,19R,26aS)
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 <sub>43</sub> <sup>13</sup> CH <sub>67</sub> D <sub>2</sub> NO <sub>12</sub>
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	Conforms to structure	Conforms
MS	Conforms to structure	Conforms
<sup>1</sup> H NMR	Conforms to structure	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% <sup>13</sup> C
Water Content (KF)	N/A	0.3%
Optical Rotation	N/A	[a] <sub>D</sub> <sup>20.0</sup> (c=0.43, CHCl <sub>3</sub> ): -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.