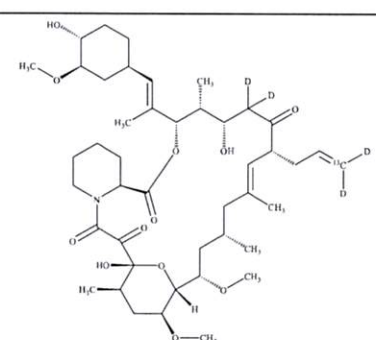


Certificate of Analysis



 Certificate No.: **20260513020**

Date: May 13, 2026

Retest date: April 30, 2029

Compound Name:	Tacrolimus-¹³C-d₄	
Synonyms:	(3S,4R,5S,8R,9E,12S,14S,15R,16S,18R,19R,26aS)-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-methylethenyl]-14,16-dimethoxy-4,10,12,18-tetramethyl-8-(2-propen-1-yl)-3- ¹³ C-2,2-d ₂ -15,19-epoxy-3H-pyrido[2,1-c][1,4]oxaazacyclotricosine-1,7,20,21(4H,23H)-tetrone-6,6-d ₂	
TLC Catalogue Number:	T-3960	
CAS Number:	N/A	
Alternate CAS Number:	104987-11-3 (non-labelled)	
Molecular Weight:	809.05	
Molecular Formula:	C ₄₃ ¹³ CH ₆₅ D ₄ NO ₁₂	
Source:	TLC Pharmaceutical Standards	
Source Lot No.:	7382-067A3	
Storage Conditions:	Store at 2-8 °C	
Solubility:	Methanol, DMSO, Acetonitrile	

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%	97.7%
Impurity (HPLC)	RT 4.80, 0.43%; RT 8.08, 0.32%; RT 11.71, 1.16%	
Isotopic Enrichment	Not less than 98.0%	99.0% D; 99.0% ¹³C
Optical Rotation	N/A	$[\alpha]_D^{20.0}(c=0.35, \text{CHCl}_3)$: -83.5°
Residual Solvents (NMR)	No residual solvent	
Assay (qNMR)	Not less than 90.0%	93.0%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		05/13/2026
Approved by:	Quality Assurance		05/13/2026

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