CERTIFICATE OF ANALYSIS

(Certificate No. KMT007013-01)

Release Date: 30/09/2023 **Re-test Date:** 29/09/2026

Tacrolimus 8-Propyl Analog Impurity

Identification

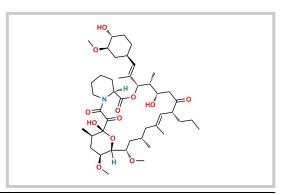
Chemical Name:

Hexadecahydro-5,19-dihydroxy-3- $\{(E)$ -2- $\{(1R,3R,4R)$ -4-hydroxy-3-methoxycyclohexyl $\}$ -1-methylvinyl $\}$ -14,16-dimethoxy-4,10,12,18-tetramethyl-15,19-epoxy-8-propyl-3H-pyrido $\{(2,1-c)\}$ [1,4]oxaazacyclotricosine-1,7,20,21(4H,23H)-tetrone (as per USP)

Alt. Name : Tacrolimus 8-Propyl Analog (USP)

CAT No. : KMT007013 **CAS No.** : 104987-30-6 **Molecular Formula** : C44H71NO12

Molecular Weight : 806.0



Analytical Information

Description: Off White SolidMass: ConfirmHPLC Purity: 93.72 %IR: ConfirmWeight Loss By TGA: 1.00 %1H NMR: Confirm

% Potency : 92.78 %

Additional Information

Long Term Storage : Store at 2-8 deg. C for long term storage

Shipping Condition: Product is stable to be Shipped at Room Temperature

% Potency = [100 - 1.00(Weight Loss By TGA)] x [93.72(HPLC Purity)]/100 = 92.78 %

Remarks: COA Re-generated on 22.10.2024

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		22/10/2024
Reviewed & Approved By	Quality Control	Jatin Patel		22/10/2024

Attachments: COA, HPLC, MASS, 1HNMR, IR and TGA