

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 :

(3S,4R,5S,8R,9E,12S,14S,15R,16S,18R,19R,26aS)-5,19-Dihydroxy-3-[(1E)-1-[(1R,3R,4R)-4-hydroxy-3-methoxycyclohexyl]prop-1-en-2-yl]-14,16-dimethoxy-4,10,12,18-tetramethyl-8-propyl-3,4,5,6,8,11,12,13,14,15,16,17,18,19,24,25,26,26a-octadecahydro-7H-15,19-epoxypyrido[2,1-c][1,4]oxaazacyclotricosine-1,7,20,21(23H)-tetrone (as per EP);(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-{(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)

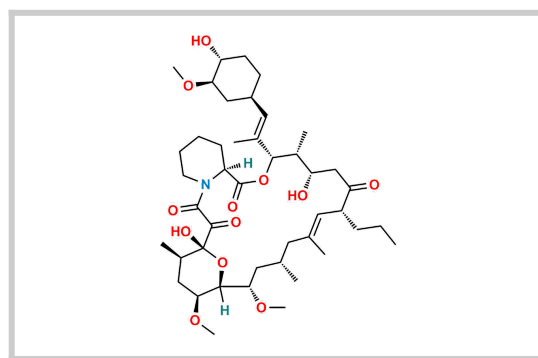
Alt. Name : Tacrolimus 8-Propyl Analog (USP)

CAT No. : KMT007013

CAS No. : 104987-30-6

Molecular Formula : C₄₄H₇₁NO₁₂

Molecular Weight : 806.0



Analytical Information

Batch No. : TAC-8-PRO-011-115

Description : Off White Solid

HPLC Purity : 93.72 %

Weight Loss By TGA : 1.00 %

% Potency : 92.78 %

Solubility : Acetonitrile

Mass : Confirm

IR : Confirm

¹H NMR : Confirm

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