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CERTIFICATE OF ANALYSIS

Analysis Date: Apr 2024

Re-test Date: Mar 2027

Product Name: Tacrolimus EP Impurity A

Identification:

Chemical Name: (3S,4R,5S,8R,9E,12S,14S,15R,16S,18R,19R,26aS)-8-Ethyl-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-3,4,5,6,8,11,12,13,14,15,16,17,18,19,24,25,26,26a-octadecahydro-7H-15,19-epoxyprido[2,1-c][1,4]oxaazacyclotricosine-1,7,20,21(23H)-tetrone (as per EP)

Synonyms : Tacrolimus Desmethylene Impurity

CAS Number : 104987-12-4

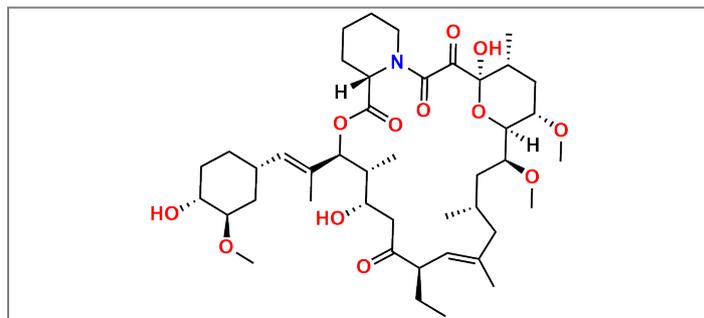
CAT Number : CP-T39001

Molecular Formula : C₄₃H₆₉N₂O₁₂

Molecular Weight : 792.02

Batch Number : CP-TAC-A-0424

Shipping condition : At low temperature with dry ice and ice pack gel



Analytical Information:

Sr. No.	Test	Result
1)	Description	White Solid
2)	Solubility	Soluble in Methanol/DMSO
3)	MASS By LCMS	Confirm to structure
4)	Purity By HPLC	96.19%
5)	¹ HNMR	Confirm to structure
6)	Weight loss by TGA	0.922%
7)	Potency by TGA	95.3%



Prepared and Reviewed By

Ms Priyanka Salunkhe
(Quality Control)

Approved By

Ms Rohini Gagare
(Quality Assurance)

Note: Product supplied by Chemicea are for R&D purpose only and not for human consumptions.