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## **CERTIFICATE OF ANALYSIS**

Analysis Date: Apr 2024

Re-test Date: Mar 2027

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## 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-epoxypyrido[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	HO	
Molecular Formula	: C43H69NO12		
Molecular Weight	: 792.02		
Batch Number	: CP-TAC-A-0424		
Storage Condition	: Tightly closed, Inert atmosphere	Tightly closed, Inert atmosphere at -20° C	
Shipping condition	: At low temperature with dry ice a	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)	H1NMR	Confirm to structure	
6)	13CNMR	Confirm to structure	
7)	Weight loss by TGA	0.922%	
8)	Potency by TGA	95.3%	

Prepared and Reviewed By

Approved By





Ms Priyanka Salunkhe (Manager QC Analytical)

Ms Rohini Gagare (QA Head)

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