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CERTIFICATE OF ANALYSIS

Analysis Date:

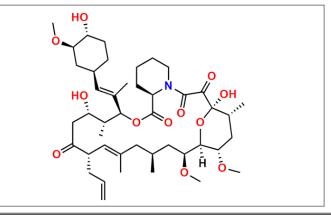
Re-test Date:

Product Name: Tacrolimus EP Impurity D

Identification:

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

Synonyms	: Tacrolimum 8-Epimer (USP) ; 8- epi-Tacrolimus
CAS Number	: 129212-35-7
CAT Number	: CP-T39004
Molecular Formula	: C44H69NO12
Molecular Weight	: 804



Analytical Information:

Sr. No.	Test	Result
1)	Description	Solid
2)	Solubility	Soluble in Methanol/DMSO
3)	MASS By LCMS	Confirm to structure
4)	Purity By HPLC	>95%
5)	H1NMR	Confirm to structure



Prepared and Reviewed By

Ms Priyanka Salunkhe (Manager QC Analytical)

Approved By

Ms Rohini Gagare (QA Head)

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