CERTIFICATE OF ANALYSIS

(Certificate No. KMT007012-01)

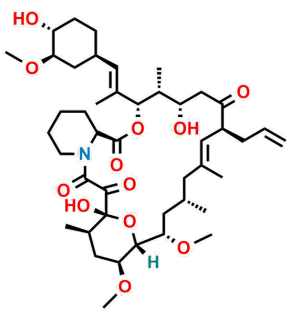
Release Date: 08/12/2025 **Re-test Date:** 07/12/2028

8-Epi Tacrolimus

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-3-methoxycyclohexyl]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[2,1-c][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-3-methoxycyclohexyl]-1-methylvinyl}-14,16-dimethoxy-4,10,12,18-tetramethyl-15,19-epoxy-3H-pyrido[2,1-c][1,4]oxaazacyclotricosine-1,7,20,21(4H,23H)-tetrone (as per USP)

Alt. Name	: Tacrolimum 8-Epimer (USP) ; 8-epi-Tacrolimus
CAT No.	: KMT007012
CAS No.	: 129212-35-7
Molecular Formula	: C44H69NO12
Molecular Weight	: 804.0



Analytical Information

Batch No.	: TAC-8-EPI-011-114	**Solubility**	: Acetonitrile
Description	: Off White Solid	**Mass**	: Confirm
HPLC Purity	: 93.82 %	**IR**	: Confirm
Weight Loss By TGA	: 2.58 %	**1H NMR**	: Confirm
% Potency	: 91.4 %		

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 - 2.58(Weight Loss By TGA)] x [93.82(HPLC Purity)]/100 = 91.4 %
-Re-tested on 08.12.2025

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		08/12/2025
Reviewed & Approved By	Quality Control	Jatin Patel		08/12/2025

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