

# CERTIFICATE OF ANALYSIS

(Certificate No. KMT007012-01)

Release Date: 08/12/2025

Re-test Date: 07/12/2028

## Tacrolimus 8-epimer

### 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)

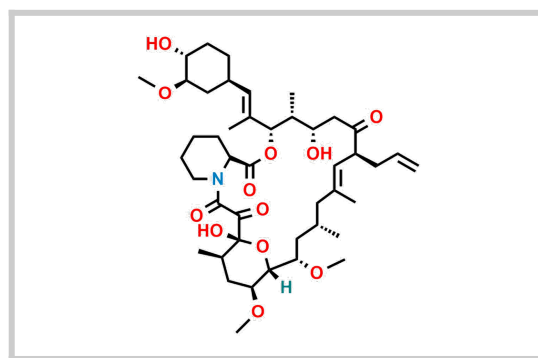
**Alt. Name** : Tacrolimum 8-Epimer (USP) ; 8-epi-Tacrolimus

**CAT No.** : KMT007012

**CAS No.** : 129212-35-7

**Molecular Formula** : C<sub>44</sub>H<sub>69</sub>N<sub>2</sub>O<sub>12</sub>

**Molecular Weight** : 804.0



### Analytical Information

**Batch No.** : TAC-8-EPI-011-114

**Description** : Off White Solid

**HPLC Purity** : 93.82 %

**Weight Loss By TGA** : 2.58 %

**% Potency** : 91.4 %

**Solubility** : Acetonitrile

**Mass** : Confirm

**IR** : Confirm

**<sup>1</sup>H 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 - 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		10/12/2025
Reviewed & Approved By	Quality Control	Jatin Patel		10/12/2025

**Attachments** : COA, HPLC, MASS, <sup>1</sup>HNMR, IR and TGA