

# CERTIFICATE OF ANALYSIS

(Certificate No. KMT007018-01)

Release Date: 24/09/2024

Re-test Date: 23/09/2027

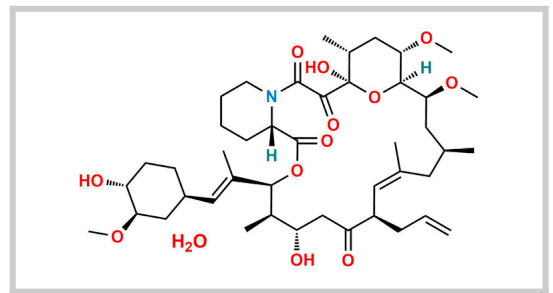
## Tacrolimus Hydrate

### Identification

**Chemical Name :**

(3S,4R,5S,8R,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-epoxy-pyrido[2,1-c][1,4]oxaazacyclotricosine-1,7,20,21(23H)-tetrone monohydrate (as per EP); (-)-(3S,4R,5S,8R,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 monohydrate (as per USP)

CAT No. : KMT007018  
CAS No. : 109581-93-3  
Molecular Formula : C<sub>44</sub>H<sub>69</sub>NO<sub>12</sub> : H<sub>2</sub>O  
Molecular Weight : 804.0 : 18.0



### Analytical Information

Batch No.	: EB02/S5/24/073	Solubility	: Methanol
Description	: White Solid	Mass	: Confirm
		IR	: Confirm
		<sup>1</sup> H NMR	: Confirm
		<sup>13</sup> C NMR	: Confirm
		DEPT 135	: 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 - ] x []/100 = 0 %  
Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		25/09/2024
Reviewed & Approved By	Quality Control	Jatin Patel		25/09/2024