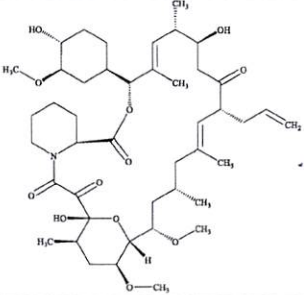


## Certificate of Analysis

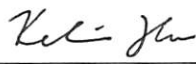

Certificate No.: 20241113505

Date: November 13, 2024

Retest date: November 12, 2027

<b>Compound Name:</b>	<b>Tacrolimus Impurity 2</b>	
<b>Synonyms:</b>	[3R-[3R(1R,3R,4R),4E,6S,7S,10R,11E,14S,16S,17R,18S,20R,21R,28aS]]-7,8,10,13,14,15,16,17,18,19,20,21,26,27,28,28a-hexadecahydro-7,21-dihydroxy-3-(4-hydroxy-3-methoxycyclohexyl)-16,18-dimethoxy-4,6,12,14,20-pentamethyl-10-(2-propenyl)-17,21-Epoxy-3H-pyrido[2,1-c][1,4]oxaazacyclopentacosine-1,9,22,23(6H,25H)-tetrone	
<b>TLC Catalogue Number:</b>	T-399	
<b>CAS Number:</b>	131944-48-4	
<b>Molecular Weight:</b>	804.03	
<b>Molecular Formula:</b>	C <sub>44</sub> H <sub>69</sub> NO <sub>12</sub>	
<b>Source:</b>	TLC Pharmaceutical Standards	
<b>Source Lot No.:</b>	5003-015A8	
<b>Storage Conditions:</b>	Store at 2-8 °C	
<b>Solubility:</b>	Methanol, DMSO, DMF, Acetonitrile	

Test Description	Specifications	Results
<b>Visual Description</b>	White to off-white solid	<b>Conforms</b>
<b>Identification</b>		
IR	Conforms to structure	<b>Conforms</b>
MS	Conforms to structure	<b>Conforms</b>
<sup>1</sup> H NMR	Conforms to structure	<b>Conforms</b>
<b>Purity (HPLC)</b>	Not less than 90.0%	<b>97.7%</b>
<b>Impurity (HPLC)</b>	RT 14.35, 0.48%; RT 20.61, 0.57%; RT 22.57, 0.38%	
<b>Water Content (KF)</b>	N/A	<b>0.7%</b>
<b>Residual Solvents (NMR)</b>	1.1% acetone	
<b>Assay (%)</b>	Not less than 85.0%	<b>95.9%</b>
<b>Recommendation:</b>	<b>Release.</b>	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		11 / 14 / 2024
Approved by:	Quality Assurance		11 / 14 / 2024

**Attachments:** HPLC, IR, MS and NMR spectra.