

Certificate of Analysis

Tacrolimus Monohydrate

CAS No.	109581-93-3	Code	BIOJTCM001
Lot No	260154FK	Manufacture Date	Jan.19, 2026
Expiry Date	Jan.18, 2029	Quantity	100G

Testing Items	Specifications	Results
Appearance	White crystals or white crystalline powder	White crystalline powder
Identification	A: Infrared absorption	Complies
	B: The retention time of the major peak of the sample solution corresponds to that of the standard solution as obtained in the assay	Complies
Residue on ignition	$\leq 0.1\%$	0.0%
Heavy metals	$\leq 10\text{ppm}$	$< 10\text{ppm}$
Optical rotation	-110° to -115°	-112°
Water	$\leq 4.0\%$	1.9%
Related substances	Ascomycin 19-epimer $\leq 0.1\%$ Ascomycin $\leq 0.50\%$ Desmethyl tacrolimus $\leq 0.1\%$ Tacrolimus 8-epimer $\leq 0.15\%$ Tacrolimus 8-propyl analog $\leq 0.15\%$ Any individual unspecified impurity $\leq 0.1\%$ Total impurities $\leq 1.0\%$	Not detected Not detected Not detected Not detected 0.05% Not detected 0.0%
Content of tautomers	Tautomers I $\leq 0.5\%$ Tautomers II $\leq 1.0\%$ Sum of tautomers I and tautomers II $\leq 1.0\%$	0.3% 0.5% 0.8%
Assay	98.0%~102.0% (on the anhydrous and solvent-free basis)	99.8%
Residual solvent	Ethanol $\leq 2000\text{ppm}$ Ethyl acetate $\leq 2000\text{ppm}$ N-Heptane $\leq 2000\text{ppm}$	12ppm Not detected Not detected
*Note: Total impurities does not include tacrolimus open ring (Tautomer I) and tacrolimus 19-epimer (Tautomer II)		
Conclusion	This product conforms to current USP standard	

***Storage condition: Store below 25°C, Protect from moisture and light.**