

Certificate of Analysis

Tacrolimus Monohydrate

CAS No.	109581-93-3	Code	BIOJTCM001
Lot No	HNTN2508502U	Manufacture Date	Aug.11, 2025
Retest Date	Aug.10, 2028	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	≤0.1%	0.04%
Heavy metals	≤10ppm	<10ppm
Optical rotation	-110° to -115°	-111°
Water	≤4.0%	2.2%
Organic impurities	Ascomycin 19-epimer≤0.1% Ascomycin≤0.50% Desmethyl tacrolimus≤0.1% Tacrolimus 8-epimer≤0.15% Tacrolimus 8-propyl analog≤0.15% Any individual unspecified impurity≤0.1% Total impurities≤1.0%	Not detected Not detected Not detected Not detected 0.07% Not detected 0.1%
Assay	98.0%~102.0% (on the anhydrous and solvent-free basis)	100.5%
Residual solvent	Ethanol≤0.5% Acetone≤0.5% Ethyl acetate≤0.5% Isopropyl ether≤0.05%	Not detected Not detected 0.01% Not detected
Conclusion	This product conforms to current USP standard	

***Storage condition: Store between 2°C~8°C, Protect from moisture and light.**