

## Certificate of Analysis

### Tacrolimus Monohydrate

CAS No.	109581-93-3	Code	BIOJTCM001
Lot No	HNTN2410502U	Manufacture Date	Oct.13, 2024
Retest Date	Oct.12, 2027	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	$\leq 0.1\%$	0.04%
Heavy metals	$\leq 10\text{ppm}$	$< 10\text{ppm}$
Optical rotation	$-110^{\circ}$ to $-115^{\circ}$	$-111^{\circ}$
Water	$\leq 4.0\%$	2.0%
Organic impurities	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 0.05%
Assay	98.0%~102.0% (on the anhydrous and solvent-free basis)	100.1%
Residual solvent	Ethanol $\leq 0.5\%$ Acetone $\leq 0.5\%$ Ethyl acetate $\leq 0.5\%$ Isopropyl ether $\leq 0.05\%$	Not detected Not detected Not detected Not detected
Conclusion	This product conforms to current USP standard	

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