

Certificate of analysis

Tacrolimus Monohydrate

CAS No.	104987-11-3	Code	BIOJTCM001
Lot No	HNTN2404502U	Manufacture Date	Apr.21, 2024
Retest Date	Apr.20, 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	≤0.1%	0.05%
Heavy metals	≤10ppm	<10ppm
Optical rotation	-110 ° to -115 °	-111 °
Water	≤4.0%	2.1%
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 Not detected Not detected Not detected
Assay	98.0%~102.0% (on the anhydrous and solvent-free basis)	100.0%
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.**