

CERTIFICATE OF ANALYSIS

Product Name:	Tacrolimus monohydrate		
Batch No.	AJ230701B	Report Date	August 9, 2023
Manufacturing Date	July 3, 2023	Expiry Date	July 2, 2025
Quantity	2286.000Gram	Quality Standard	USP
Analytical results			
Items	Specifications		Results
Appearance	White crystals or white crystalline powder.		White crystalline powder
Identification	A. Infrared spectroscopy: The infrared spectroscopy is concordant with that of the reference standard.		Conform
	B. HPLC: The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay.		Conform
Organic impurities	Ascomycin 19-epimer $\leq 0.1\%$		ND
	Ascomycin $\leq 0.50\%$		0.07%
	Desmethyl Tacrolimus $\leq 0.1\%$		ND
	Tacrolimus 8-epimer $\leq 0.15\%$		ND
	Tacrolimus 8-propyl analog $\leq 0.15\%$		ND
	Any individual unspecified impurity $\leq 0.1\%$		0.09%
	Total impurities $\leq 1.0\%$		0.20%
Optical rotation	$-110^\circ \sim -115^\circ$		-114°
Water determination	$\leq 4.0\%$		2.10%
Residue on ignition	$\leq 0.1\%$		$< 0.1\%$
Residual solvents	Ethanol $\leq 0.5\%$		ND
	Acetone $\leq 0.5\%$		$< 0.1\%$
	Ethyl acetate $\leq 0.5\%$		ND
	Isopropanol $\leq 0.5\%$		ND
	Acetonitrile $\leq 0.041\%$		ND
	Toluene $\leq 0.089\%$		ND
	Methanol $\leq 0.3\%$		ND
	Isopropylbenzene (Cumene) $\leq 0.007\%$		ND
	Benzene $\leq 0.0002\%$		$< 0.0001\%$
Microbiological contamination	TAMC ≤ 1000 cfu/g		< 10 cfu/g
	TYMC ≤ 100 cfu/g		< 10 cfu/g
	E-Coli should not be detected on 1g.		ND
Assay	98.0%~102.0% (on anhydrous and solvent-free basis)		99.80%
Storage	Store in dry place, avoid direct sunlight.		
Conclusion	This product conforms to USP standard.		

Inspector: Carlifor Wu

Verifier: Jack He