Certificate of Analysis

Product name: Tacrolimus monohydricus
Batch number / Weight: 26A16-B13-020676 / 500 mg
Producer / Producer Batch Number: Wuxi Fortune Pharmaceutical Co., Ltd / AJ251201D
Analyzed according to: Ph.Eur. 12.1
Number of Analysis / Certificate no.: 26A16-B13 / QO0029853

	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification	Conform	Conform		
Appearance of solution	Clear / <= GY7			
Related substances	Conform	Conform		
Impurity A	<=0,5	<0,05	%	
Unspecified impurities	each <=0,15	<0,05	%	
Total impurities	<=1,0	<0,05	%	
Water	1,5 - 4,0	2,3	%	
Sulfated ash	<=0,1	0,0	%	
Assay	97,0 - 102,0	101,7	% m/m	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
TSE/BSE-statement:	EMA/410/01 guidance compliant – no contamination	Conform		

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FSNE LAB

Release:

18-3-2026
Ewelina Gadzinowska
Qualified Person

Expiration: 4-12-2028
Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

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