Certificate of Analysis

Product name: Tacrolimus monohydricus
Batch number / Weight: 25C07-B03-009034 / 500 mg
Producer / Producer Batch Number: Wuxi Fortune Pharmaceutical Co., Ltd / AJ241002C
Analyzed according to: Ph. Eur. 11.7
Number of Analysis / Certificate no.: 25C07-B03 / QO0014315

	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification	Conform	Conform		
Appearance of solution	Clear / <= GY7	Conform		
Related substances	Conform	Conform		
Impurity A	<=0,5	0,10	%	
Unspecified impurities	each <=0,15	0,051	%	
Total impurities	<=1,0	0,15	%	
Water (Karl Fischer)	1,5 - 4,0	2,18	%	
Sulfated ash	<=0,1	0,02	%	
Assay	97,0 - 102,0	100,61	% m/m	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		DP

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:

15-4-2025
Dominika Sołtysik
Qualified Person

Expiration: 21-10-2027
Conclusion: APPROVED

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

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