Certificate of Analysis

Product name: **Tacrolimus monohydricus**

Batch number / Weight: **22E04-B02-226457 / 500 MG**

Analysed according to: **USP**

Number of analysis / Inspection Code **22E04-B02-218331 / INS-22-4830**

Reference Code / No.: **V01844 / P/TAC/22/04/005**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Identification	Conform	Conform		
Organic impurities	Conform	Conform		
Ascomycin 19-epimer	<=0,1	<0,05	%	
Ascomycin	<=0,50	0,396	%	
Desmethyl Tacrolimus	<=0,1	0,00	%	
Tacrolymus 8-epimer	<=0,15	0,000	%	
Tacrolymus 8-propyl analog	<=0,15	0,121	%	
Any other impurity	<=0,1	<0,05	%	
Total impurities	<=1,0	0,52	%	
Water (Karl Fischer)	<=4,0	2,21	%	
Residue on ignition	<=0,1	0,01	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Tacrolimus	98,0 - 102,0 (anhydrous)	99,38	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Acetone		4,26	ppm	
Ethyl acetate	<=2000	4,52	ppm	
Di-isopropyl ether	<=100	29,7	ppm	
Acetonitrile		9,75	ppm	
Toluen	<=250	2,76	ppm	
Hexane	<=250	0,45	ppm	

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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 Own lab

Release:
Ewelina Gadzinowska
Qualified Person

30-11-2022

Expiration: 31-03-2025

Conclusion: APPROVED

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