

Certificate of Analysis

Product name: Fagron Convenience Pack TO

Batch number: 25G10-H05-72054

Analysed according to: IHS

Analytical records Tacrolimus monohydricus 24K28-B06-008291

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification	IR spectrum	Conform		
Appearance of solution	Clear/≤ GY7	Conform		
Related substances	Conform	Conform		
Impurity A	≤ 0,5	0,12	%	
Unspecified impurities	each ≤ 0,15	0,076	%	
Total impurities	≤ 1,0	0,19	%	
Water (Karl Fisher)	1,5 - 4,0	2,28	%	
Sulfated ash	≤ 0,1	0,00	%	
Assay	97,0 - 102,0	100,21	% 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

Analysis performed by the authorized lab FSNE lab.

Meets the requirements of the PH.EUR 11.7

Analytical records Orafix® 25E14-H10-00665

Tests	Requirement	Result	Unit	Standard remark
Appearance	Semi-solid with characteristic creamy-brown colour, uniform, without visible impurities, slightly granular to the touch	Conform		
Odour	Characteristic	Conform		
Identification	Conform	Conform		IR
Viscosity	6000 - 12000	10580	cPs	50°C; R6 100rpm
Microbial contamination	Conform	Conform		
Total Aerobic Microbial Count (TAMC)	≤ 200	<10	CFU/g	
Total Yeasts and Moulds Count (TYMC)	≤ 20	<10	CFU/g	
Escherichia Coli	Absent	Conform		
Staphylococcus aureus	Absent	Conform		
Pseudomonas aeruginosa	Absent	Conform		
Candida albicans	Absent	Conform		

Analysis performed by the authorized internal lab and by the authorized lab QACS.

Meets the requirements of the IHS

Release:

Konstantina Tziolia

Pharmacist - QA Manager / QP

10/07/2025

Expiration: 25/02/2027

Conclusion: APPROVED

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