

Certificate of Analysis

Product name: Fagron Advanced Derma Pack TT

Batch number: 25H19-H01-72092

Analysed according to: IHS

Analytical records Tacrolimus monohydricus 25C07-B03-009035

Tests	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 Fisher)	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	Conform		DP

Analysis performed by the authorized lab FSNE lab

Meets the requirements of the PH.EUR 11.7

Analytical records Trichosol™ 25D22-H13-00695

Tests	Requirement	Result	Unit	Standard remark
Appearance	Cloudy clear liquid	Conform		
Colour	Colourless to yellow	Conform		
Odour	Characteristic	Conform		
Density	0,990 - 1,030	1,024	g/ml	20°C
pH	1,50 - 2,50	2,09		
Impurities	Exempt	Conform		
TSE/ BSE-statement	No contamination with TSE/BSE-risk materials	Conform		

Analysis performed by the authorized internal lab.

Meets the requirements of the IHS

Release:

Konstantina Tziolia

Pharmacist - QA Manager / QP

19/08/2025

Expiration: 22/07/2026

Conclusion: APPROVED

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