Certificate of Analysis

Product name: **Fagron Advanced Derma Pack HTTN**

Batch number: **26A13-H04-72083**

Analysed according to: **IHS**

Analytical records Hydroquinone 24L11-H08-00291

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, white crystal needles or white, crystalline powder	Conform		
Identification A	Conform	Conform		IR
Identification B	Conform	Conform		TLC
Identification C	Conform	Conform		UV
Melting point	172,0 - 174,0	172,0	°C	
Water	<= 0,5	0,00	%	
Residue on ignition	<= 0,5	0,01	%	
Assay Hydroquinone	99,0 - 100,5	99,5	%	
TSE/BSE-statement	No contamination with TSE/BSE-risk materials	Conform		

Analysis performed by the authorized internal lab.

Meets the requirements of the USP 43.

Analytical records Nourivan antiox™ 26A07-H04-00542

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, stiff, shiny, homogeneous mass	Conform		
Odour	Specific, not perfumed	Conform		
Identification A	Conform	Conform		Benzoic acid; HPLC
Assay Benzoic acid	0,06 - 0,12	0,09	%	
Identification B	Conform	Conform		Sorbic acid; HPLC
Assay Sorbic acid	0,06 - 0,12	0,09	%	
pH	2,5 - 5,5	3,36		
Density	0,97 - 1,00	0,97	g/ml	
Yield value	100 - 400	262	Pa	
Microbial contamination	Conform	Conform		
Total Aerobic Microbial Count (TAMC)	<= 100	<10	CFU/g	
Total Yeasts and Moulds Count (TYMC)	<= 10	<10	CFU/g	
Pseudomonas aeruginosa	Absent	Absent	/g	
Staphylococcus aureus	Absent	Absent	/g	
Residual solvents	ICH Q3C	Conform		
Metallic residues	ICH Q3D	Conform		
TSE/BSE-statement	No contamination with TSE/BSE-risk materials	Conform		

Fagron Hellas - Kertus ICSA - 12 km N.R. Trikala-Larissa - P.C. 42100 Trikala - Hellas P.O. Box 32
Tel. +30 (0) 24310 83633-5 - Fax +30 (0) 24310 83615 - info@fagron.gr

Analysis performed by the authorized internal lab, by the authorized lab of Fagron a.s. (CZ) and by the authorized lab QACS.

Meets the requirements of the IHS

Analytical records Tretinoin 25G29-B03-014647

Tests	Requirement	Result	Unit	Standard remark
Appearance	Yellow or light orange, crystalline powder	Conform		
Identification	A	Conform		
Related substances	Conform	Conform		
Impurity A	<=0,5	0,00	%	
Unspecified impurities	<=0,2	<0,05	%	
Total impurities	<=1,0	0,18	%	
Loss on drying	<= 0,5	0,00	%	
Sulfated ash	<= 0,1	0,06	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay	98,0 - 102,0	99,02	% m/m	
TSE/BSE-statement:	EMA/410/01 guidance compliant – no contamination	Conform		
TAMC	<=10^3	<10^2	cfu/g	
TYMC	<=10^2	<10^1	cfu/g	

Analysis performed by the authorized lab FSNE

Meets the requirements of the PH.EUR 11.8.

Analytical records Triamcinolone acetonide 25G03-H05-00785

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or almost white, crystalline powder	Conform		
Solubility	Practically insoluble in water, sparingly soluble in ethanol	Conform		
Identification A	Conform	Conform		IR
Identification C	Conform	Conform		Assay
Specific optical rotation	+110,0 - +117,0	+113		
Related substances	Conform	Conform		HPLC
Impurity B	<= 0,2	<0,05	%	
Impurity C	<= 0,15	0,046	%	
Impurity E	<= 0,15	<0,05	%	
Unspecified impurities	<= 0,10	<0,05	%	
Total impurities	<= 0,5	0,05	%	
Water	<= 2,0	0,0	%	
Assay Triamcinolone acetonide	97,5 - 102,0	99,71	%m/m	Anhydrous substance

Residual solvents	Conform	Conform	
Acetone	<= 1000	78	ppm
Methanol	<= 900	258	ppm
Dichloromethane	<= 400	ND	ppm
Particle size	99% <10µm	100	%
Particle size	70% <5µm	90	%
TSE/BSE-statement	No contamination with TSE/BSE-risk materials	Conform	

Analysis performed by the authorized internal lab and by the authorized lab of Fagron Services Northern Europe Sp.zo.o..

Meets the requirements of the PH.EUR 11.7

Release:
Konstantina Tziolia
Pharmacist - QA Manager / QP

13/01/2026

Expiration: 31/01/2027

Conclusion: APPROVED

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