

Certificate of Analysis

Product name: **Fluocinoloni acetonidum micr.**

Batch number / Weight: **22D11-B02-221615 / 1 G**

Analysed according to: **Ph.Eur.10**

Number of analysis / Inspection Code **22D11-B02 / INS-22-5369**

Reference Code / No.: **V01457 / 2151NM1 B0032123**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white crystalline powder	Conform		
Particle size	99%<30 µm and 95%<15 µm	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Specific optical rotation	+100 - +104	+101,5		
Related substances	Conform	Conform		
Impurity K	<=0,3	<0,05	%	
Impurity D	<=0,2	<0,05	%	
Impurity H	<0,15	<0,05	%	
Impurity I	<0,15	<0,05	%	
Impurity J	<=0,2	0,068	%	
Any impurity	<=0,10	<0,05	%	
Total impurities	<=0,7	0,07	%	
Loss on drying	<=1,0	0,59	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		
Metallic residues	CHMP/ICH/353369/2013	Conform		
Assay Fluocinolone acetonide	97,5 - 102,0	100,64	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		
Residual solvents				
Methanol		<3000	ppm	
Acetone	<5000 ppm	<5000	ppm	
Dichloromethane		<600	ppm	

fagron.pl

Fagron Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:biuro@fagron.pl

fagron.pl

Fagron sp. z o.o.
ul. Pasternik 26, 31-354 Kraków, Poland
tel.: +48 12 3343 512
e-mail: biuro@fagron.pl

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 Fagron PL lab

Release:
Dominika Soltysik
Qualified Person

16-09-2022

Expiration: 16-06-2026

Conclusion: APPROVED

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

fagron.pl

Fagron Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:biuro@fagron.pl