

Certificate of Analysis

Product name: **Fluocinoloni acetonidum micr.**

Batch number / Weight: **21K03-B06-218729 / 1 G**

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

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	+102	°	
Related substances	Conform	Conform		
Impurity K	<=0,3	<0,05	%	
Impurity D	<=0,2	0,19	%	
Impurity H	<0,15	<0,05	%	
Impurity I	<0,15	<0,05	%	
Impurity J	<=0,2	<0,05	%	
Any impurity	<=0,10	<0,05	%	
Total impurities	<=0,7	0,19	%	
Loss on drying	<=1,0	0,79	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Fluocinolone acetonide	97,5 - 102,0	101,5	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Agnieszka Pszczółka
Qualified Person

20-03-2022

Expiration: 28-02-2026

Conclusion: APPROVED

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