

Certificate of Analysis

Product name: **Triamcinolonum micronisatum**

Batch number / Weight: **22A17-B05-218505 / 5 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white crystalline powder	Conform		
Particle size	$\geq 99\%$ $< 25 \mu\text{m}$ / $\geq 90\%$ $< 10 \mu\text{m}$	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Specific optical rotation	+65 - +72	+70		
Related substances	Conform	Conform		
Any impurity	≤ 1	0,61	%	
Max. 2 impurities $\geq 0,5\%$	≤ 2	Conform		
Total impurities	≤ 2	1,2	%	
Water (Karl Fischer)	$\leq 1,0$	0,4	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Triamcinolone	97,0 - 103,0	98,2	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Methanol	not more than 1500 ppm	506	ppm	
Acetone	not more than 3000 ppm	26	ppm	

Analysis performed by the authorized lab.

Release:
Dominika Sołtysik
Qualified Person

08-05-2022

Expiration: 10-09-2026

Conclusion: APPROVED

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