

## Certificate of Analysis

**Product name:** **Triamcinolonum micronisatum**

**Batch number / Weight:** **18J01-B05-219955 / 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	+67		
Related substances	Conform	Conform		
Any impurity	$\leq 1$	$< 1$	%	
Max. 2 impurities $\geq 0,5\%$	$\leq 2$	Conform		
Total impurities	$\leq 2$	$< 2$	%	
Water (Karl Fischer)	$\leq 1,0$	0,3	%	
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	98,0	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:  
Ewelina Gadzinowska  
Qualified Person

23-04-2022

Expiration: 30-06-2023

Conclusion: APPROVED

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