

Certificate of Analysis

Product name: **Triamcinoloni acetonidum micr.**

Batch number / Weight: **21H04-B13-216475 / 5 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white crystalline powder	Conform		
Particle size	99% <25 µm / 90% <10 µm	Conform	%	
Identification A	Conform	Conform		
Identification C	Conform	Conform		
Specific optical rotation	+110 - +117	+113	°	
Related substances	Conform	Conform		
Impurity B	<=0,2	<0,05	%	
Impurity C	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,5	<0,05	%	
Water (Karl Fischer)	<=2,0	1,39	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Triamcinolone acetone	97,5 - 102,0	100,8	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Methanol		97		
Acetone		64		
Dichloromethane		50		

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

20-12-2021

Expiration: 28-02-2026

Conclusion: APPROVED

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