

Certificate of Analysis

Product name: **Triamcinolonum micronisatum**

Batch number / Weight: **22J05-B05-224115 / 5 G**

Analysed according to: **Ph.Eur.10.8**

Number of analysis / Inspection Code **22J05-B05 / INS-22-8629**

Reference Code / No.: **V00619 / NTL220602**

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	+67,9		
Related substances	Conform	Conform		
Any impurity	≤ 1	0,4	%	
Max. 2 impurities $\geq 0,5\%$	≤ 2	Conform		
Total impurities	≤ 2	1,4	%	
Water (Karl Fischer)	$\leq 1,0$	0,16	%	
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	99,47	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Methanol	not more than 1500 ppm	<3000	ppm	
Acetone	not more than 3000 ppm	<5000	ppm	

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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:

Agnieszka Pszczółka

Qualified Person

14-11-2022

Expiration: 31-05-2027

Conclusion: APPROVED

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