

Certificate of Analysis

Product name: Triamcinolonum micronisatum
Batch number / Weight: 19J10-F02-215437 / 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 B	Conform	Conform		
Specific optical rotation	+65 - +72	+70	°	
Related substances	Conform	Conform		
Any impurity	<=1	0,3	%	
Max. 2 impurities >=0,5%	<=2	Conform		
Total impurities	<=2	0,8	%	
Water (Karl Fischer)	<=1,0	0,2	%	
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	98,9	%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

28-09-2021

Expiration: 31-08-2024

Conclusion: APPROVED

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