

Certificate of Analysis

Productname: Triamcinolonum micronisatum
Number of analysis/Inspection Code: 1 / KEUR-185833B
Batchnumber: 19J10-F02-373474
Reference code / No.: 1980 / NTL 190902
Analysed according to: PH.EUR9.8+

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		IR-spectrum
Identification B	Conform	Conform		TLC
Specific optical rotation	+65 - +72	+70		1% m/V in DMF; anhydrous
Related substances	Conform	Conform		HPLC
Any impurity	≤ 1	0,3	%	
Max. 2 impurities $\geq 0,5\%$	≤ 2	Conform		
Total impurities	≤ 2	0,8	%	
Water (Karl Fischer)	$\leq 1,0$	0,2	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Triamcinolone	97,0 - 103,0	98,9	%m/m	Anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
Paul Hofman
Pharmacist - Qualified Person

09/22/20

Expiration: 08-2024

Conclusion: APPROVED

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