

Certificate of Analysis

Productname: Triamcinoloni acetonidum micr.
Number of analysis/Inspection Code: 1 / KEUR-180641B
Batchnumber: 18K16-B05-367959
Reference code / No.: 4095 / NY2097M
Analysed according to: PH.EUR9.5+

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white crystalline powder	Conform		
Particle size	99% <25 µm / 90% <10 µm	Conform	%	Laser
Identification A	Conform	Conform		IR-spectrum
Identification C	Conform	Conform		HPLC
Specific optical rotation	+110 - +117	+115		0.5% <i>m/V</i> in EtOH; anhydrous
Related substances	Conform	Conform		HPLC
Impurity B	<=0,2	<0,05	%	
Impurity C	<=0,15	0,05	%	
Unspecified impurities	<=0,10	0,05	%	
Total impurities	<=0,5	0,10	%	
Water (Karl Fischer)	<=2,0	0,9	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Triamcinolone acetonide	97,5 - 102,0	99,5	% <i>m/m</i>	Anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
dr. M.J. Vincenten - van Maanen
Pharmacist - Qualified Person

02/21/20

Expiration: 07-2023

Conclusion: APPROVED

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