

Certificate of Analysis

Productname: Diflucortoloni valeras micron.
Number of analysis/Inspection Code: 1 / KEUR-180665B
Batchnumber: 19L23-F04-367879
Reference code / No.: 2073 / 2139VM0 C0071822
Analysed according to: BP2019+

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, (almost) white powder	Conform		
Particle size	99% <20 µm / 95% <10 µm	Conform		
Identification A	Conform	Conform		UV-spectrum
Identification B	Conform	Conform		IR-spectrum
Specific optical rotation	+98 - +103	+101		1% <i>m/V</i> dioxane; dried
Related substances	Conform	Conform		HPLC
Any impurity	<=1	0	%	
Total impurities	<=2	1	%	
Loss on drying	<=0,5	0,1	%	105 °C
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Diflucortolon valerate	97,0 - 102,0	101,4	% <i>m/m</i>	Dried
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

02/24/20

Expiration: 10-2023

Conclusion: APPROVED

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