

Certificate of Analysis

Product name: **Diflucortoloni valeras micron.**

Batch number / Weight: **21J13-B05-213974 / 5 G**

Analysed according to: **BP**

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	+99	°	1% <i>m</i> /V in dioxane, anhydrous
Related substances	Conform	Conform		HPLC
Any impurity	≤1	0,33	%	
Total impurities	≤2	0,52	%	
Loss on drying	≤0,5	0,05	%	105 °C
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Diflucortolon valerate	97,0 - 102,0	101,6	% <i>m</i> /m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

20-01-2022

Expiration: 30-09-2025

Conclusion: APPROVED

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