

Certificate of Analysis

Product name: **Diflucortoloni valeras micron.**

Batch number / Weight: **22A20-B01-217330 / 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		
Identification B	Conform	Conform		
Specific optical rotation	+98 - +103	+103		
Related substances	Conform	Conform		
Any impurity	<=1	0,25	%	
Total impurities	<=2	0,41	%	
Loss on drying	<=0,5	0,04	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay Diflucortolon valerate	97,0 - 102,0	99,7	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		
Residual solvents				
Methanol	<=3000	<25	ppm	
Ethanol	not more than 2000 ppm	<25	ppm	
Acetone	not more than 3000 ppm	<25	ppm	
Methylene chloride	<=600	11	ppm	
Tetrahydrofurane		<25	ppm	
Isopropyl ether	<=200	<4	ppm	
Isopropenyl acetate	<=200	<4	ppm	
Methyl isobuthyl ketone	<=2000	<40	ppm	
Pyridine		<4	ppm	
Dimethylformamide	<880 ppm	<15	ppm	

Analysis performed by the authorized lab.

Release:

Ewelina Gadzinowska

Qualified Person

27-05-2022

Expiration: 30-04-2026

Conclusion: APPROVED

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