Certificate of Analysis

Product name: **Diflucortoloni valeras micron.**

Batch number / Weight: **22K12-B03-223840 / 5 G**

Analysed according to: **British Pharmacopoeia**

Number of analysis / Inspection Code **22K12-B03 / INS-22-9565**

Reference Code / No.: **V01456 / 2139VM0 C0072222**

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	+99,2		
Related substances	Conform	Conform		
Any impurity	<=1	0,4	%	
Total impurities	<=2	1,1	%	
Loss on drying	<=0,5	0,09	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay Diflucortolon valerate	97,0 - 102,0	98,83	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		
Residual solvents				
Methanol	<=3000	<3000	ppm	
Ethanol	<=5000	<5000	ppm	
Acetone	<=5000	<5000	ppm	
Methylene chloride	<=600	0,0	ppm	
Tetrahydrofurane	<=720	0,0	ppm	
Methyl isobuthyl ketone	<=4500	0,0	ppm	
Pyridine	<=200	0,0	ppm	
Dimethylformamide	<880 ppm	<880	ppm	

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FAGRON PL lab

Release:
Dominika Sołtysik
Qualified Person

18-01-2023

Expiration: 13-07-2027

Conclusion: APPROVED

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