

## Certificate of Analysis

**Product name:** **Diflucortoloni valeras micron.**

**Batch number / Weight:** **22E24-B01-222460 / 1 G**

**Analysed according to:** **British Pharmacopoeia**

**Number of analysis / Inspection Code** **22E24-B01 / INS-22-4879**

**Reference Code / No.:** **V01456 / 2139VM0 C0022222**

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	+99,4		
Related substances	Conform	Conform		
Any impurity	<=1	0,4	%	
Total impurities	<=2	1,1	%	
Loss on drying	<=0,5	0,12	%	
Assay Diflucortolon valerate	97,0 - 102,0	97,75	%m/m	
Residual solvents				
Methanol	<=3000	<3000	ppm	
Ethanol	<=5000	<5000	ppm	
Acetone	<=5000	<5000	ppm	
Methylene chloride	<=600	<600	ppm	
Tetrahydrofurane	<=720	0,00	ppm	
Methyl isobutyl ketone	<=4500	0,00	ppm	
Pyridine	<=200	0,00	ppm	
Dimethylformamide	<=200	0,00	ppm	

fagron.pl

Fagron Sp. z o.o.  
 ul. Armii Krajowej 3  
 32-540 Trzebinia, Poland  
 e-mail: biuro@fagron.pl

fagron.pl

Fagron sp. z o.o.  
 ul. Pasternik 26, 31-354 Kraków, Poland  
 tel.: +48 12 3343 512  
 e-mail: biuro@fagron.pl

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

Release:  
Dominika Soltysik  
Qualified Person

21-09-2022

Expiration: 28-03-2027

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.