

## Certificate of Analysis

**Product name:** **Hydrocortisonum micronisatum**

**Batch number / Weight:** **22E09-B04-225531 / 100 G**

**Analysed according to:** **Ph.Eur.10.8**

**Number of analysis / Inspection Code** **22E09-B04 / INS-22-4179**

**Reference Code / No.:** **V00603 / K05M20210104M**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, (almost) white powder	Conform		
Particle size	99% < 25 µm / 90% < 10 µm	Conform		
Identification A	Conform			
Identification B	Conform			
Specific optical rotation	+162 - +168 (dried substance)	+165,5		
Related substances	Conform	Conform		
Impurity C	<=0,5	0,07	%	
Impurity D	<=0,5	0,05	%	
Impurity E	<=0,5	<0,05	%	
Impurity I	<=0,5	<0,05	%	
Impurity G	<=0,4	0,09	%	
Impurity F	<=0,3	<0,05	%	
Impurity A	<=0,2	<0,05	%	
Impurity B	<=0,2	<0,05	%	
Impurity H	<=0,15	<0,05	%	
Impurity N	<=0,15	0,053	%	
Unspecified impurities	<=0,10	0,046		
Total impurities	<=2,0	0,31	%	
Loss on drying	<=1,0	0,01	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	97,0 - 103,0 (dried substance)	100,31	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Acetone	not more than 3000 ppm	925	ppm	
Methanol	not more than 1500 ppm	<30	ppm	
Dichloromethane	not more than 100 ppm	<30		

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 EL Spol

Release:

Agnieszka Pszczółka

Qualified Person

31-10-2022

Expiration: 31-12-2025

Conclusion: APPROVED

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

fagron.pl

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