

## Certificate of Analysis

**Product name:** Hydrocortisonum micronisatum  
**Batch number / Weight:** 21G16-B06-216623 / 25 G  
**Analysed according to:** Ph. Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, (almost) white powder	Conform		
Particle size	99% < 25 µm / 90% < 10 µm	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Specific optical rotation	+162 - +168 (dried substance)	+168		
Related substances	Conform	Conform		
Impurity C	≤0,5	0,06	%	
Impurity D	≤0,5	0,07	%	
Impurity E	≤0,5	<0,05	%	
Impurity I	≤0,5	<0,05	%	
Impurity G	≤0,4	0,17	%	
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	<0,05	%	
Unspecified impurities	≤0,10	0,06	%	
Total impurities	≤2,0	0,36	%	
Loss on drying	≤1,0	0,07	%	
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)	98,3	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Methanol	≤3000	Conform	ppm	
Acetone	≤5000	Conform	ppm	
Dichloromethane	≤600	Conform	ppm	

Analysis performed by the authorized lab.

Release:  
Ewelina Gadzinowska

Qualified Person

28-10-2021

Expiration: 31-12-2025

Conclusion: APPROVED

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