

Certificate of Analysis

Product name: **Hydrocortisonum micronisatum**

Batch number / Weight: **22E09-B02-222588 / 100 G**

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

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		
Identification	Conform	Conform		
Specific optical rotation	+162 - +168 (dried substance)	+162,4		
Related substances	Conform	Conform		
Impurity C	<=0,5	0,05	%	
Impurity D	<=0,5	0,06	%	
Impurity E	<=0,5	<0,05	%	
Impurity I	<=0,5	<0,05	%	
Impurity G	<=0,4	0,11	%	
Impurity F	<=0,3	<0,05	%	
Impurity A	<=0,2	0,07	%	
Impurity B	<=0,2	<0,05	%	
Impurity H	<=0,15	<0,05	%	
Impurity N	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	0,05	%	
Total impurities	<=2,0	0,34	%	
Loss on drying	<=1,0	0,05	%	
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)	100,62	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Methanol	<=3000	<3000	ppm	
Acetone	<=5000	<5000	ppm	
Dichloromethane	<=600	<600	ppm	

Analysis performed by the authorized lab.

Release:

Agnieszka Pszczółka

Qualified Person

20-07-2022

Expiration: 31-12-2025

Conclusion: APPROVED

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