

Certificate of Analysis

Product name: **Hydrocortisonum micronisatum**

Batch number / Weight: **21J26-B07-218141 / 25 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, (almost) white powder	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

Analysis performed by the authorized lab.

Release:
Dominika Soltysik
Qualified Person

10-03-2022

Expiration: 31-12-2025

Conclusion: APPROVED

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