

Certificate of Analysis

Product name: **Hydrocortisonum micronisatum**

Batch number / Weight: **21J26-B07-216690 / 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)	+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				
Acetone	not more than 3000 ppm	1384	ppm	
Methanol	not more than 1500 ppm	nd	ppm	
Dichloromethane	not more than 100 ppm	nd		

Analysis performed by the authorized lab.

Release:

Ewelina Gadzinowska

Qualified Person

16-03-2022

Expiration: 31-12-2025

Conclusion: APPROVED

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