

Certificate of Analysis

Product name: Hydrocortisonum micronisatum
Batch number / Weight: 21D12-B07-213312 / 5 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)	+166,0		
Related substances	Conform	Conform		
Impurity C	<=0,5	<0,05	%	
Impurity D	<=0,5	0,05	%	
Impurity E	<=0,5	<0,05	%	
Impurity I	<=0,5	0,00	%	
Impurity G	<=0,4	0,07	%	
Impurity F	<=0,3	<0,05	%	
Impurity A	<=0,2	<0,05	%	
Impurity B	<=0,2	<0,05	%	
Impurity H	<=0,15	0,00	%	
Impurity N	<=0,15	0,062	%	
Unspecified impurities	<=0,10	0,089	%	
Total impurities	<=2,0	0,35	%	
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)	100,58	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
 Ewelina Gadzinowska
 Qualified Person

11-08-2021

Expiration: 28-02-2025

Conclusion: APPROVED

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