

Certificate of Analysis

Product name: Hydrocortisonum micronisatum
Batch number / Weight: 20E14-B11-201660 / 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		
Identification	Conform	Conform		
Specific optical rotation	+162 - +168 (dried substance)	+163,5	°	
Related substances	Conform	Conform		
Impurity C	<=0,5	0,08	%	
Impurity D	<=0,5	0,05	%	
Impurity E	<=0,5	0,00	%	
Impurity I	<=0,5	0,00	%	
Impurity G	<=0,4	0,06	%	
Impurity F	<=0,3	0,00	%	
Impurity A	<=0,2	0,10	%	
Impurity B	<=0,2	0,00	%	
Impurity H	<=0,15	<0,05	%	
Impurity N	<=0,15	0,05	%	
Unspecified impurities	<=0,10	0,05	%	
Total impurities	<=2,0	0,40	%	
Loss on drying	<=1,0	0,10	%	
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)	100,41	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Dorota Sutkowska
Qualified Person

17-07-2020

Expiration: 28-02-2025

Conclusion: APPROVED

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