

Certificate of Analysis

Product name: Hydrocortisonum micronisatum
Batch number / Weight: 21G16-B06-215276 / 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)	+168		
Related substances	Conform	Conform		
Impurity C	<=0,5	0,06	%	
Impurity D	<=0,5	0,07	%	
Impurity E	<=0,5	<0,05	%	
Impurity I	<=0,5	<0,05	%	
Impurity G	<=0,4	0,17	%	
Impurity F	<=0,3	<0,05	%	
Impurity A	<=0,2	<0,05	%	
Impurity B	<=0,2	<0,05	%	
Impurity H	<=0,15	<0,05	%	
Impurity N	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	0,06	%	
Total impurities	<=2,0	0,36	%	
Loss on drying	<=1,0	0,07	%	
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)	98,3	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Methanol	<=3000	Conform	ppm	
Acetone	<5000	Conform	ppm	
Dichloromethane	<=600	Conform	ppm	

Analysis performed by the authorized lab.

Release:
 Ewelina Gadzinowska

Qualified Person

08-10-2021

Expiration: 31-12-2025

Conclusion: APPROVED

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