

Certificate of Analysis

Product name: Hydrocortisonum micronisatum

Batch number / Weight: 22J19-B02-226695 / 25 G

Analysed according to: Ph.Eur.11.0

Number of analysis / Inspection Code 22J19-B02 / INS-22-8817

Reference Code / No.: V00603 / K05M20211101M

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)	+163,2		
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	<0,05	%	
Impurity G	<=0,4	0,09	%	
Impurity F	<=0,3	<0,05	%	
Impurity A	<=0,2	0,06	%	
Impurity B	<=0,2	<0,05	%	
Impurity H	<=0,15	0,000	%	
Impurity N	<=0,15	0,059	%	
Unspecified impurities	<=0,10	0,073	%	
Total impurities	<=2,0	0,33	%	
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)	101,17	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Methanol	<=3000	<3000	ppm	
Acetone	<=5000	<5000	ppm	

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Dichloromethane	<=600	<600	ppm
Acetic acid	<= 0,5% (LOD)	Conform	

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL, ElSpol

Release:

Ewelina Gadzinowska

Qualified Person

19-01-2023

Expiration: 31-10-2026

Conclusion: APPROVED

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