

Certificate of Analysis

Productname: Hydrocortisonum micronisatum
Number of analysis/Inspection Code: 1 / KEUR-180829B
Batchnumber: 18I19-B06-367906
Reference code / No.: 1991 / K05M20170414M
Analysed according to: PH.EUR9.5+

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		IR-spectrum
Identification B	Conform	Conform		HPLC
Specific optical rotation	+162 - +168	+164		0,8% <i>m/V</i> MeOH; dried
Related substances	Conform	Conform		HPLC
Impurity C	<=0,5	<0,1	%	
Impurity D	<=0,5	<0,1	%	
Impurity E	<=0,5	<0,1	%	
Impurity I	<=0,5	nd	%	
Impurity G	<=0,4	<0,1	%	
Impurity F	<=0,3	<0,1	%	
Impurity A	<=0,2	<0,1	%	
Impurity B	<=0,2	<0,1	%	
Impurity H	<=0,15	nd	%	
Impurity N	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	0,05	%	
Total impurities	<=2,0	0,1	%	
Loss on drying	<=1,0	0,2	%	105 °C
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay Hydrocortisone	97,0 - 103,0	101,1	% <i>m/m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Quercus BE.

Release:

dr. M.J. Vincenten - van Maanen

Pharmacist - Qualified Person

02/28/20

Expiration: 03-2022

Conclusion: APPROVED

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