

Certificate of Analysis

Productname: Hydrocortisoni acetat micr.
Number of analysis/Inspection Code: 1 / KEUR-185170B
Batchnumber: 20F26-F01-371743
Reference code / No.: 1980 / NCEHAC 200508-1
Analysed according to: PHEUR10.2+

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white crystalline powder	Conform		
Particle size	99% < 25 µm / 90% < 10 µm	Conform		Microscopy
Identification A	Conform	Conform		IR-spectrum
Identification B	Conform	Conform		HPLC
Specific optical rotation	+158 - +167	+167		1% <i>m</i> /V in dioxane; dried
Related substances	Conform	Conform		HPLC
Impurity C	<=0,6	0,2	%	
Impurity A	<=0,5	0,1	%	
Impurity B	<=0,3	<0,05	%	
Impurity D	<=0,3	0,2	%	
Impurity E	<=0,3	0,0	%	
Impurity G	<=0,15	0,00	%	
Unspecified impurities	<=0,10	0,05	%	
Total impurities	<=1,5	0,4	%	
Loss on drying	<=0,5	0,0	%	3 h 60°C in vacuo
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Hydrocortisone acetate	97,0 - 102,0	99,8	% <i>m</i> /m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
Paul Hofman
Pharmacist - Qualified Person

08/20/20

Expiration: 04-2023

Conclusion: APPROVED

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