

Certificate of Analysis

Product name: **Cortisoni acetat micronisatum**

Batch number / Weight: **21H06-B07-221786 / 5 G**

Analysed according to: **Ph. Eur. 10.8**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, (almost) white powder	Conform		
Particle size	99%<25µm 90%<10µm	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Specific optical rotation	+211 - +220	+216,4		
Related substances	Conform	Conform		
Impurity A	<=0,5	0,00	%	
Total impurities	<=1,5	0,41	%	
Loss on drying	<=0,5	0,09	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Cortison acetate	97,0 -103,0	98,99	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

18-08-2022

Expiration: 31-12-2024

Conclusion: APPROVED

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