

Certificate of Analysis

Product name: **Hydrocortisoni acetat micr.**

Batch number / Weight: **21J07-B09-216290 / 1 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	(almost) white, crystalline powder	Conform		
Particle size	99% < 25 µm / 90% < 10 µm	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Specific optical rotation	+158 - +167	+165,1		
Related substances	Conform	Conform		
Impurity A	<=0,5	<0,05	%	
Impurity B	<=0,3	<0,05	%	
Impurity C	<=0,6	0,18	%	
Impurity D	<=0,3	0,11	%	
Impurity E	<=0,3	<0,05	%	
Impurity G	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	0,05	%	
Total impurities	<=1,5	0,39	%	
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	97,0 - 102,0	100,03	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Agnieszka Pszczółka
Qualified Person

22-12-2021

Expiration: 12-03-2024

Conclusion: APPROVED

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