

Certificate of Analysis

Product name: Hydrocortisoni acetat micr.
Batch number / Weight: 22A17-B07-213778 / 10 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	+158,6		
Related substances	Conform	Conform		
Impurity A	<=0,5	<0,05	%	
Impurity B	<=0,3	<0,05	%	
Impurity C	<=0,6	0,23	%	
Impurity D	<=0,3	0,10	%	
Impurity E	<=0,3	0,11	%	
Impurity G	<=0,15	0,00	%	
Unspecified impurities	<=0,10	0,055	%	
Total impurities	<=1,5	0,50	%	
Loss on drying	<=0,5	0,02	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	97,0 - 102,0	98,62	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Chloroform	<=60	<60	ppm	
Dimethylformamide	<=880	<860	ppm	

Analysis performed by the authorized lab.

Release:

Agnieszka Pszczółka

Qualified Person

29-04-2022

Expiration: 26-10-2024

Conclusion: APPROVED

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