

Certificate of Analysis

Product name: **Prednisoloni acetat micro.**

Batch number / Weight: **21H18-B06-213235 / 1 G**

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

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		
Identification B	Conform	Conform		
Specific optical rotation	+128 - +137	+128,4	°	
Related substances	Conform	Conform		
Impurity A	<=1,0	0,13	%	
Impurity B	<=1,0	0,36	%	
Impurity C	<=0,5	<0,05	%	
Unspecified impurities	<=0,10	0,069	%	
Total impurities	<=2,0	0,56	%	
Loss on drying	<=0,5	0,11	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Assay Prednisolone acetate	97,0 - 103,0	101,08	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Dominika Sołtysik
Qualified Person

29-12-2021

Expiration: 31-01-2026

Conclusion: APPROVED

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