

Certificate of Analysis

Product name: **Prednisoloni acetat micro.**

Batch number / Weight: **20J01-F12-217210 / 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	+133	°	
Related substances	Conform	Conform		
Impurity A	≤1,0	0,2	%	
Impurity B	≤1,0	0,7	%	
Impurity C	≤0,5	<0,05	%	
Unspecified impurities	≤0,10	0,08	%	
Total impurities	≤2,0	1,0	%	
Loss on drying	≤0,5	0,2	%	
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	100,9	%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

21-01-2022

Expiration: 28-02-2025

Conclusion: APPROVED

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