

Certificate of Analysis

Product name: Prednisolonum micronisatum
Batch number / Weight: 20H20-B01-204179 / 25 G
Analysed according to: Ph.Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, (almost) white powder, hygroscopic	Conform		
Particle size	99% < 25 µm / 90% < 10 µm	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Specific optical rotation	+113 - +119	+115,5		
Related substances	Conform	Conform		
Impurity A	<=1,0	0,28	%	
Impurity B	<=0,3	<0,05	%	
Impurity C	<=0,3	<0,05	%	
Impurity F	<=0,5	<0,05	%	
Impurity J	<=0,3	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=1,5	0,28	%	
Loss on drying	<=1,0	0,12	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Prednisolone	96,5 - 102,0	99,29	%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

02-02-2021

Expiration: 01-07-2023

Conclusion: APPROVED

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