

Certificate of Analysis

Product name: Prednisolonum micronisatum
Batch number / Weight: 21C03-B05-210451 / 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	+118,1		
Related substances	Conform	Conform		
Impurity A	≤1,0	0,40	%	
Impurity B	≤0,3	0,06%	%	
Impurity C	≤0,3	<0,05%	%	
Impurity F	≤0,5	<0,05%	%	
Impurity J	≤0,3	<0,05%	%	
Unspecified impurities	≤0,10	<0,10	%	
Total impurities	≤1,5	0,61	%	
Loss on drying	≤1,0	0,27	%	
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	99,2	%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

29-06-2021

Expiration: 21-12-2023

Conclusion: APPROVED

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