

Certificate of Analysis

Product name: **Prednisonum micronisatum**

Batch number / Weight: **22A14-B08-213380 / 25 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance		Conform		
Particle size		Conform		
Identification A		Conform		
Identification C		Conform		
Specific optical rotation		+188,5		
Related substances		C		
Impurity A		0,14	%	
Impurity E		0,06	%	
Impurity D		0,00	%	
Unspecified impurities	<=0,10	0,075	%	
Total impurities	<=1,0	0,37	%	
Loss on drying		0,10	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay		99,96	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Acetone	<5000 ppm	<5000	ppm	

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

18-03-2022

Expiration: 04-09-2023

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.