

Certificate of Analysis

Product name: **Dexamethasonum micronisatum**

Batch number / Weight: **21H13-B20-213352 / 1 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance		Conform		
Particle size		Conform		
Identification A		Conform		
Identification B		Conform		
Specific optical rotation		+87,8		
Related substances		Conform		
Impurity G		<0,05	%	
Impurity B		<0,05	%	
Impurity F		<0,05	%	
Impurity J		<0,05	%	
Impurity K		<0,05	%	
Unspecified impurities		<0,05	%	
Total impurities		0,00	%	
Loss on drying		0,16	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay		100,93	%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

24-01-2022

Expiration: 07-06-2023

Conclusion: APPROVED

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