

Certificate of Analysis

Product name: **Methylprednisolonum micr.**

Batch number / Weight: **22D14-B07-218846 / 1 G**

Analysed according to: **Ph.Eur.10.8**

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	+97,0 - +103,0	+97,1		
Related substances	Conform	Conform		
Impurity D	<=0,5	<0,05	%	
Impurity A	<=0,3	0,06	%	
Impurity G and I	<=0,3	0,00	%	
Impurity H	<=0,2	<0,05	%	
Impurity B	<=0,2	<0,05	%	
Impurity C	<=0,15	<0,05	%	
Impurity E	<=0,15	0,00	%	
Impurity F	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	0,053	%	
Total impurities	<=2,0	0,16	%	
Loss on drying	<=1,0	0,30	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Methylprednisolone	97,0 - 102,0	100,10	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Methanol		<3000	ppm	
Dichloromethane		<600	ppm	
Chloroform		<60	ppm	

Analysis performed by the authorized lab.

Release:

Ewelina Gadzinowska

Qualified Person

25-07-2022

Expiration: 30-11-2025

Conclusion: APPROVED

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