Certificate of Analysis

Product name: **Methylprednisolonum micr.**

Batch number / Weight: **21F02-B09-213784 / 5 G**

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

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	98,5	°	
Related substances	Conform	Conform		
Impurity D	<=0,5	<0,05	%	
Impurity A	<=0,3	<0,05	%	
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	<0,05	%	
Total impurities	<=2,0	0,00	%	
Loss on drying	<=1,0	0,34	%	
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	99,21	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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Fagron sp. z o.o.
ul. Pasternik 26, 31-354 Kraków, Poland
tel.: +48 12 3343 512
e-mail: biuro@fagron.pl

Analysis performed by the authorized lab.

Release:
Dominika Sołtysik
Qualified Person

05-01-2022

Expiration: 05-01-2025

Conclusion: APPROVED

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