Certificate of Analysis

Product name: **Methylprednisolonum micr.**

Batch number / Weight: **22D14-B07-222965 / 1 G**

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

Number of analysis / Inspection Code **22D14-B07 / INS-22-4224**

Reference Code / No.: **V00619 / NXEMP211209-1**

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	<3000	ppm	
Dichloromethane	<= 600	<600	ppm	
Chloroform	<= 60	<60	ppm	

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Fagron Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:biuro@fagron.pl

fagron.pl

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

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FAGRON PL lab

Release:
Ewelina Gadzinowska
Qualified Person

18-10-2022

Expiration: 30-11-2025

Conclusion: APPROVED

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Fagron Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail:biuro@fagron.pl