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Certificate of Analysis

Productname: **Methylprednisolonum micr.**

Number of analysis/Inspection Code: 1 / KEUR-187013B

Batchnumber: **20J13-F08-374714**

Reference code / No.: 1980 / NXEMP200703

Analysed according to: **PHEUR10.2+**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, (almost) white crystalline powder	Conform		
Particle size	99% < 25 µm / 90% < 10 µm	Conform		Microscopy
Identification A	Conform	Conform		IR-spectrum
Identification B	Conform	Conform		HPLC
Specific optical rotation	+97,0 - +103,0	+99,5		1%m/V in dioxane; anhydrous
Related substances	Conform	Conform		HPLC
Impurity D	<=0,5	<0,05	%	
Impurity A	<=0,3	<0,05	%	
Impurity G and I	<=0,3	0,0	%	
Impurity H	<=0,2	<0,05	%	
Impurity B	<=0,2	0,0	%	
Impurity C	<=0,15	<0,05	%	
Impurity E	<=0,15	0,00	%	
Impurity F	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	0,07	%	
Total impurities	<=2,0	0,1	%	
Loss on drying	<=1,0	0,4	%	105°C
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Methylprednisolone	97,0 - 102,0	100,0	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
CEP	CEP available	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
Paul Hofman
Pharmacist - Qualified Person

11/13/20

Expiration: 06-2024

Conclusion: APPROVED

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