Certificate of Analysis

Product name: **Prasteronum**

Batch number / Weight: **22K21-B05-223816 / 50 G**

Analysed according to: **Ph.Fr.**

Number of analysis / Inspection Code **22K21-B05 / INS-22-9530**

Reference Code / No.: **V01950 / DHEAH220601 W**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Yellow-)white, crystalline powder	Conform		
Identification B	Conform	Conform		
Spezifische Drehung	+11,0 - +14,0	+12,50		
Related substances	Conform	Conform		
Impurity A	<=0,1	0,00	%	
Impurity B	<=0,1	0,00	%	
Impurity D	<=0,1	0,00	%	
Impurity E	<=0,1	<0,025	%	
Impurity C	<=0,02	0,00	%	
Impurity F	<=0,08	0,00	%	
Any other impurity	<=0,1	0,069	%	
Total impurities	<=0,5	0,14	%	
Hydroxylamine	<=5	Conform	ppm	
Sulphated ash	<=0,1	0,01	%	
Water	<=1,0	0,05	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay Prasterone	97,5 - 102,0	99,98	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		

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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:
Agnieszka Pszczółka
Qualified Person

21-12-2022

Expiration: 01-06-2024

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

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