

Certificate of Analysis

Product name: **Prasteronum**
Batch number / Weight: **22K21-B05-223838 / 1 KG**
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	$\leq 0,1$	0,00	%	
Impurity B	$\leq 0,1$	0,00	%	
Impurity D	$\leq 0,1$	0,00	%	
Impurity E	$\leq 0,1$	$< 0,025$	%	
Impurity C	$\leq 0,02$	0,00	%	
Impurity F	$\leq 0,08$	0,00	%	
Any other impurity	$\leq 0,1$	0,069	%	
Total impurities	$\leq 0,5$	0,14	%	
Hydroxylamine	≤ 5	Conform	ppm	
Sulphated ash	$\leq 0,1$	0,01	%	
Water	$\leq 1,0$	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		

fagron.pl 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 Eurofins

Release:

Agnieszka Pszczółka

Qualified Person

21-12-2022

Expiration: 01-06-2024

Conclusion: APPROVED

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