

## Certificate of Analysis

**Product name:** **Hydroxyprogesteronum (11-alfa)**

**Batch number / Weight:** **23A10-B06-224406 / 5 G**

**Analysed according to:** **Monograph**

**Number of analysis / Inspection Code** **23A10-B06 / INS-23-1166**

**Reference Code / No.:** **V01951 / C23-220908**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder or colourless crystals	Conform		
Melting point	About 168	168	°C	
Identification	Conform	Conform		
Related substances	<=1	<1	%	
Loss on drying	<= 0,5	0,2	%	
Hydroxyprogesteron 11-alfa	97,0 - 103,0	97,6	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
Residual solvents				
Acetone	<= 2000	<25	ppm	
Petroleum ether	<= 2000	<10	ppm	

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 EL Spol

Release:  
Ewelina Gadzinowska  
Qualified Person

17-04-2023

Expiration: 20-09-2025

Conclusion: APPROVED

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

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