

Certificate of Analysis

Product name: Hydroxyprogesteronum (11-alfa)

Batch number / Weight: 23A10-B06-233694 / 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	0,22	%	
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 Own lab

Release:
Ewelina Gadzinowska
Qualified Person

11-12-2023

Expiration: 20-09-2025

Conclusion: APPROVED

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