Certificate of Analysis

Product name: **Fludrocortisoni acetas micr.**

Batch number / Weight: **22A14-B03-230293 / 1 G**

Analysed according to: **Ph.Eur.11.2**

Number of analysis / Inspection Code **22A14-B03 / INS-22-1442**

Reference Code / No.: **V01457 / 2142AM0 B0041923**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(almost) white, crystalline powder	Conform		
Particle size	99% < 25 µm / 90% <10 µm	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Specific optical rotation	+148 - +156	+151,3		
Related substances	Conform	Conform		
Any impurity	<=1,0	0,13	%	
Total impurities	<=1,5	0,34	%	
Loss on drying	<=1,0	0,13	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Fludrocortisone acetate	97,0 - 103,0	98,65	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Methanol	<= 3000	<3000	ppm	
Ethanol	<= 5000	<5000	ppm	
Dichloromethane	<= 600	0,0	ppm	
Ethyl acetate	<= 5000	<5000	ppm	
Tetrahydrofurane	<= 720	<720	ppm	
Pyridine	<= 200	0,0	ppm	
Dimethylformamide	<880 ppm	0,0	ppm	

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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:
Dominika Sołtysik
Qualified Person

11-09-2023

Expiration: 31-01-2025

Conclusion: APPROVED

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