

Certificate of Analysis

Product name: **Fludrocortisoni acetat micr.**
Batch number / Weight: **22A14-B03-216763 / 300 MG**
Analysed according to: **Ph. Eur.**

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	not more than 1500 ppm	<3000	ppm	
Ethanol	not more than 2000 ppm	<5000	ppm	
Dichloromethane		0,0	ppm	
Ethyl acetate	<= 5000	<5000	ppm	
Tetrahydrofurane		<720	ppm	
Pyridine		0,0	ppm	
Dimethylformamide	<880 ppm	0,0	ppm	

Analysis performed by the authorized lab.

Release:
Dominika Sołtysik
Qualified Person

28-04-2022

Expiration: 31-01-2025

Conclusion: APPROVED

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