

Certificate of Analysis

Product name: **Cortisoni acetat micronisatum**

Batch number / Weight: **21H06-B07-226332 / 5 G**

Analysed according to: **Ph. Eur. 10.8**

Number of analysis / Inspection Code **21H06-B07 / INS-21-5091**

Reference Code / No.: **V00603 / 02B20200101M**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, (almost) white powder	Conform		
Particle size	99%<25µm 90%<10µm	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Specific optical rotation	+211 - +220	+216,4		
Related substances	Conform	Conform		
Impurity A	≤0,5	0,00	%	
Total impurities	≤1,5	0,41	%	
Loss on drying	≤0,5	0,09	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Cortison acetate	97,0 -103,0	98,99	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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:
Ewelina Gadzinowska
Qualified Person

22-12-2022

Expiration: 31-12-2024

Conclusion: APPROVED

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