

Certificate of Analysis

Productname: Fludrocortisoni acetat micr.
Number of analysis/Inspection Code: 1 / KEUR-185921B
Batchnumber: 20B10-F11-373279
Reference code / No.: 2142AM0 B0011923
Analysed according to: PHEUR10.0+

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, (almost) white crystalline powder	Conform		
Particle size	99% < 25 µm / 90% <10 µm	Conform		Microscopy
Identification A	Conform	Conform		IR-spectrum
Identification B	Conform	Conform		TLC
Specific optical rotation	+148 - +156	152	°	1% <i>m</i> /V dioxane; dried
Related substances	Conform	Conform		HPLC
Any impurity	<=1,0	0,1	%	
Total impurities	<=1,5	0,3	%	
Loss on drying	<=1,0	0,1	%	105°C
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Fludrocortison acetate	97,0 - 103,0	101,2	% <i>m</i> / <i>m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Fagron Services IR.

Release:
Paul Hofman
Pharmacist - Qualified Person

09/25/20

Expiration: 03-2024

Conclusion: APPROVED

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