

Certificate of Analysis

Productname: Clobetasoli propionas micron.
Number of analysis/Inspection Code: 1 / KEUR-179857B
Batchnumber: 19J02-F02-365315
Reference code / No.: 3989 / CLO 113/0619
Analysed according to: PH.EUR9.8+

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, (almost) white powder	Conform		
Particle size	99%<25 µm / 90% <10 µm	Conform		
Identification IR-spectrum	Conform	Conform		
Specific optical rotation	+112 - +118	+114		1% <i>m/V</i> in acetone; dried
Related substances	Conform	Conform		HPLC
Impurity E	<=0,3	n.d.	%	
Impurity D	<=0,2	n.d.	%	
Impurity B	<=0,3	0,1	%	
Impurity C	<=0,3	0,1	%	
Impurity A	<=0,2	<0,05	%	
Impurity L	<=0,2	<0,05	%	
Impurity M	<=0,2	n.d.	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=1,0	0,2	%	
Loss on drying	<=0,5	0,0	%	3H 105°C
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Clobetasol 17-propionate	97,0 - 102,0	98,8	% <i>m/m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
 dr. M.J. Vincenten - van Maanen
 Pharmacist - Qualified Person

01/28/20

Expiration: 05-2024

Conclusion: APPROVED

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