

## Certificate of Analysis

**Productname:** Clobetasoli propionas micron.  
**Number of analysis/Inspection Code:** 1 / KEUR-182394B  
**Batchnumber:** 20B18-F06-369554  
**Reference code / No.:** 3989 / CLO 118/0919  
**Analysed according to:** PHEUR10.0+

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	+115		1% <i>m</i> /V in acetone; dried
Related substances	Conform	Conform		HPLC
Impurity E	<=0,3	<0,1	%	
Impurity D	<=0,2	0,1	%	
Impurity B	<=0,3	0,2	%	
Impurity C	<=0,3	<0,1	%	
Impurity A	<=0,2	<0,1	%	
Impurity L	<=0,2	<0,1	%	
Impurity M	<=0,2	<0,1	%	
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	Conform	%	
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	98,3	% <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 Steris.

Release:  
 Wai Lung Chung  
 Pharmacist - Qualified Person

05/04/20

Expiration: 08-2024

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.