

Certificate of Analysis

Product name: Clobetasoli propionas micron.
Batch number / Weight: 21I15-B06-216761 / 1 G
Analysed according to: Ph. Eur.

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	+115,5		
Related substances	Conform	Conform		
Impurity B	<=0,3	0,17	%	
Impurity E	<=0,7	0,00	%	
Impurity A	<=0,2	<0,05	%	
Impurity D	<=0,5	0,00	%	
Unspecified impurities	<=0,10	0,09	%	
Total impurities	<=2,0	0,31	%	
Loss on drying	<=0,5	0,05	%	
Sulphated ash	<=0,1	0,04	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Clobetasol 17-propionate	97,0 - 102,0	99,36	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:

CE } a • : \ a Ź • : & 5 Ź æ

Qualified Person

08-12-2021

Expiration: 31-05-2026

Conclusion: APPROVED

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