

## Certificate of Analysis

**Product name:** **Clobetasoli propionas micron.**

**Batch number / Weight:** **21L16-B08-216971 / 10 G**

**Analysed according to:** **Ph.Eur.01/2021:0195**

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	+115,3		
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:  
Agnieszka Pszczółka  
Qualified Person

03-03-2022

Expiration: 31-05-2026

Conclusion: APPROVED

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