

Certificate of Analysis

Product name: Clobetasoli propionas micron.
Batch number / Weight: 21I15-B06-213975 / 10 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:

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Qualified Person

06-12-2021

Expiration: 31-05-2026

Conclusion: APPROVED

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