

Certificate of Analysis

Product name: Clobetasoni butyras micr.

Batch number / Weight: 22A17-B11-221741 / 500 MG

Analysed according to: Ph.Eur.10

Number of analysis / Inspection Code 22A17-B11 / INS-22-2982

Reference Code / No.: V01769 / CSB 403/0621

Tests	Requirement	Result	Unit	Standard remark
Appearance		Conform		
Particle size	99% <25 µm / 90% <10 µm	Conform		
Identification	Conform	Conform		
Specific optical rotation	+127 - +133	+137		
Related substances	Conform	Conform		
Unspecified impurities	<=0,10	0,06	%	
Total impurities	<=0,5	0,06	%	
Loss on drying	<=0,5	0,02	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Clobetasone-17-butyrate	97,0 - 102,0	99,6	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Methanol	not more than 1500 ppm	<25	ppm	
Dichlorometan	<=600	<10	ppm	
Acetone	not more than 3000 ppm	<25	ppm	
Dimethylformamide	<880 ppm	<15		
Ethyl acetate	<=5000	<25		
Pyridine		7,5	%	

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL, ElSpol

Release:
Dominika Soltysik
Qualified Person

31-08-2022

Expiration: 31-05-2026

Conclusion: APPROVED

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