

Certificate of Analysis

Productname: Clobetasoli-17-propionas 1:10
Number of analysis/Inspection Code: 1 / KEUR-198223B
Batchnumber: 23A18-F06-385129
Reference code / No.: 3828 / 23A18-F06
Analysed according to: INTERN

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white to light yellow fine powder	Conform		
Identification A	Conform	Conform		TLC
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Identification D	Conform	Conform		HPLC
Loss on drying	<=15,0	9,2	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Clobetasole-17-propionate	9,50 - 10,50	10,12	%m/m	
Total aerobic microbial count (TAMC)	<10 ³	Conform	CFU / g	
Total yeasts and moulds (TYMC)	<10 ²	Conform	CFU / g	
Ps. aeruginosa	Absent	Conform	/ g	
St. aureus	Absent	Conform	/ g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Eurofins.

Manufacturer / Country : Fagron Services BV / NL
CEP :

Release:
Anthony Amoureux
Qualified Person

10/11/23

Expiration: 18-01-26

Conclusion: APPROVED

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