

Certificate of Analysis

Productname: Clobetasoli-17-propionas 1:10
Number of analysis/Inspection Code MON-204991B / KEUR-192239B
Batchnumber: 21F02-F03
Reference code / No.: 3828 / 21F02-F03
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	$\leq 15,0$	9,5	%	
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	10,02	%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

Release:
Chantal Nobus
Qualified Person

05-10-21

Expiration: 06-2024

Conclusion: APPROVED

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

Fagron Services B.V.
Molenwerf 13
Uitgeest, 1911 DB
NL

Client Account Number: A00497292BNI
Eurofins Quote Number: WB9XPH21013406

Eurofins Sample Number EB21AA3633-1			
Original Received Date:	24-Jun-2021		
Description:	Clobetasoli-17-propionas 1:10		
Lot Number:	21F02-F03		
Containers Submitted:	3 Bottle(s)		
General Method Reference: CM 15ACE438			
Analysis	Specification	Result	Unit
Appearance	White to pale yellow fine powder	white, fine powder	----
Method: 15ACE438 Analysis Date: 05-Jul-2021 to 05-Jul-2021			
Identification by TLC	The spot of sample solution and reference solution 1 fluorescent in pale orange in UV at 365nm	Meets Requirements	----
Method: 15ACE438 Analysis Date: 09-Jul-2021 to 09-Jul-2021			
Identification per reaction with sulfuric acid	After mixing, the color fades	Meets Requirements	----
Method: 15ACE438 Analysis Date: 06-Jul-2021 to 06-Jul-2021			
Identification per reaction with Iodine	The mixture turns dark blue, and after reheating yellowish	Meets Requirements	----
Method: 15ACE438 Analysis Date: 06-Jul-2021 to 06-Jul-2021			
Loss on drying	≤15%	9.5	%
Method: 15ACE438 Analysis Date: 05-Jul-2021 to 05-Jul-2021			

SPECIFICATIES
GECONTROLEERD
EN CONFORM

DATUM: 04/07/21
PARAAF: [Signature]

Analysis	Specification	Result	Unit
Assay by HPLC	9.50 - 10.50	10.06	%
	9.50 - 10.50	9.96	%
	9.50 - 10.50	9.92	%
	9.50 - 10.50	9.98	%

Begin

Method: 15ACE438

Analysis Date: 09-Aug-2021 to 11-Aug-2021

DGAT selon MH - membrane filtration	≤ 1000	180	CFU/g
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Refer to Laboratory OOS Investigation EXC-HA21AB3929

Method: Im

Analysis Date: 05-Jul-2021 to 10-Jul-2021

TYMC by filtration acc.MH	≤ 100	< 10	CFU/g
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Method: Current Ph Eur (2.6.12)

Analysis Date: 05-Jul-2021 to 10-Jul-2021

Staphylococcus aureus acc. to HM	Absence	Absence	/1 g
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Method: Current Ph Eur (2.6.13)

Analysis Date: 05-Jul-2021 to 10-Jul-2021

Pseudomonas aeruginosa acc to HM	Absence	Absence	/1 g
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Method: Current Ph Eur (2.6.13)

Analysis Date: 05-Jul-2021 to 10-Jul-2021

Assay by HPLC	9.50 - 10.50	10.10	%
	9.50 - 10.50	10.11	%
	9.50 - 10.50	9.92	%
	9.50 - 10.50	10.00	%

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Method: 15ACE438

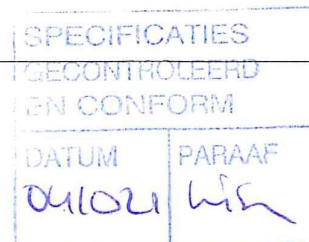
Analysis Date: 09-Aug-2021 to 11-Aug-2021

Assay by HPLC	9.50 - 10.50	10.10	%
	9.50 - 10.50	10.08	%
	9.50 - 10.50	9.98	%
	9.50 - 10.50	10.02	%

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Method: 15ACE438

Analysis Date: 09-Aug-2021 to 11-Aug-2021



Sample Compliance Assessment

EB21AA3633-1 meets the requirement(s) for all listed test(s) where specifications were applied.

Eurofins BPT Testing Facility	Test
Eurofins Pharma Quality Control Les Ulis Testing 9 Avenue de Laponie 91978 Les Ulis, Courtaboeuf Cedex FRANCE	Appearance Assay by HPLC Identification by TLC Identification per reaction with Iodine Identification per reaction with sulfuric acid Loss on drying
Eurofins Pharma Quality Control Ste Croix en Plaine 16 Rue Clément Ader 68127 Sainte-Croix-en-Plaine FRANCE	DGAT selon MH - membrane filtration Pseudomonas aeruginosa acc to HM Staphylococcus aureus acc. to HM TYMC by filtration acc.MH

Contracted Company: Eurofins Pharma Quality Control Les Ulis Testing

 9 Avenue de Laponie, Les Ulis, Courtaboeuf Cedex, 91978 France
 EPQC_ServiceClient@eurofins.com

Questions about this report should be directed to your project manager or the general email listed above.

