Diversey

Certificate of Analysis

Date 12/01/2018

Article
SKU 100934589 ClearKlens oxifast 1L sterile

batch : SEP/0001340422/17/307
expiry date : 2018/11
date of manufacture : 03/11/2017

Characteristic Method	Unit	Value	lower limit	upper limit	conformity
peracetic acid MAN LCQ 011	%	0,09	0,07	0,10	Yes
hydrogen peroxide MAN LCQ 011	%	3,10	2,90	3,40	Yes
loss TAO 16h at 96°C MAN LCQ 009	%	0,38	0,00	5,00	Yes
Sterility certificate European Pharmacopeia 2.6.1					Yes

released on : 12/01/2018 by : LALEVEE

Comments:
Sterility certificate n°171222-0015-001

The analysis results above could change over time ant in function of the storage temperature. It is imperative to store the products according to the recommended conditions indicated in the MSDS.

End of certificate of analysis

Chalon-sur-Saône, January the 12th , 2018

CERTIFICATE OF STERILITY

BIOXAL SA

Route des Varennes
BP 30072
F 71103 CHALON / SAONE
FRANCE,

Certifies that the product:

CLEARKLENS OXIFAST STERILE
Item code: 70001369
Batch number: 0001340422
Quantity: 1128 bottles,

is sterile, according to sterility test Ph.Eur. 2.6.1.

Samuel LALEVÉE
Quality Manager

Labor L+S AG Mangelsfeld 4, 5, 6 | 97708 Bad Bocklet-Großenbrach | Germany

BIOXAL S.A.
ZI sud
Cité des Varennes
71103 CHALON SUR SAÔNE
FRANKREICH

Validé le 12/01/2018

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Akkreditiert nach ISO / IEC 17025

Durch die DAkkS Deutsche Akkreditierungsstelle GmbH nach DIN EN ISO/IEC 17025 akkreditiertes Prüflaboratorium.
Die Akkreditierung gilt für die in der Urkunde aufgeführten Verfahren.

Deutsche Akkreditierungsstelle
D-PL-14559-01-01
D-PL-14559-01-02

Bad Bocklet 12 Jan 2018 / REJ / BIOXCh

Certificate of Analysis

L+S No:	171222-0015-001	**L+S Code:**	1021841 / S
Product name:	CLEARKLENS OXIFAST VH49		
Lot No:	sep/0001340422/17/307		
Entry temperature:	room temperature		
Your Order No:	4500181685		
Order dated:	20 Dec 2017		
Start of test:	27 Dec 2017	**Sample receipt:**	21 Dec 2017
		End of test:	12 Jan 2018

Sterilprüfung an "ClearKlens Oxifast VH 49, 4 Muster à 1 L"

Parameter	Specification / Demands	Result
Test procedure according to:	Ph. Eur. 2.6.1 (Produktspez. Eignungsprüfung/Methodentransfer liegt für dieses Volumen nicht vor)	
Reference document:	Growth promotion test (140225-0139-001)	
Test method:	Membrane filtration	
Test environment:	Clean room	
Number of samples tested:	4	4
Tested volume per sample:	200 ml	200 ml
Type of filter material:	PVDF (Durapore®)	PVDF (Durapore®)
Test system:	TZHVAB210	TZHVAB210
Nutrient media:	TSB & FTM with neutralisation agents (C+/T+)	C+/T+
Start of incubation:		29 Dec 2017
End of incubation:		12 Jan 2018
Period of incubation:	At least 14 days	14 days
Evaluation:	No macroscopic growth visible	**complies**

The test was conducted in compliance with GMP guidelines. There were no test-related deviations.
This document was created by a GMP-supervised LIMS and approved by electronic signature.

Approved on 12 Jan 2018 at 11:18 by Dr Maximilian Schlicht, Head of Quality Control.