



Certificate of Analysis

Date 31/07/2020

Article
SKU 100934589 ClearKlens oxifast 1L sterile

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batch: SEP/1551584/20/147
expiry date: 2022-05
date of manufacture: 26/05/2020

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	%	3,06	2,90	3,40	Yes
loss TAO 16h at 96°C MAN LCQ 009	%	0,29	0,00	2,50	Yes
Sterility certificate European Pharmacopeia 2.6.1					Yes

released on : 31/07/2020

by : LALEVEE

Comments:

Sterility certificate n° 200710-0109-001

The analysis results above could change over time and 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

CERTIFICATE OF STERILITY**BIOXAL SA**

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

Certifies that the product:

CLEARKLENS OXIFAST 1L STERILE

Item code: 70001369

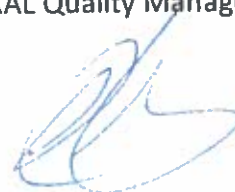
Batch number: 1551584

Quantity: 1136 bottles,

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

Samuel LALEVEE

BIOXAL Quality Manager



Valide le 31/07/2020

Labor | LS

Labor LS SE & Co. KG Mangelstfeld 4 5, 6 | 97708 Bad Bocklet | Germany

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Bad Bocklet 31 Jul 2020 / MY / BIOXCh

Certificate of Analysis

LS No:	200710-0109-001	LS Code:	1618415 / S
Product name:	Oxifast 1L		
Lot No:	SEP/1551584/20/147		
Entry temperature:	room temperature		
Order dated:	07 Jul 2020	Sample receipt:	08 Jul 2020
Start of test:	17 Jul 2020	End of test:	31 Jul 2020

Test for Sterility on "ClearKlens Oxifast VH 49, 8 samples à 1 L"

Parameter	Specification / Demands	Result
Test Procedure according to:	Ph. Eur. 2.6.1 & USP <71> (No product specific suitability test or method transfer for this filling quantity existent)	
Reference Document:	Growth Promotion Test (140225-0139-001)	
Test Method:	Membrane Filtration	
Test Environment:	Clean Room	
Number of tested Samples:	8	8
Tested Volume per Sample:	100 ml	100 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:		17 Jul 2020
End of Incubation:		31 Jul 2020
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 31 Jul 2020 at 10:17 by Katharina Schlereth, Head of Department.

Copying and disseminating and/or using excerpts of this test report is only permitted with the prior written consent of LS SE & Co. KG.

The determined results refer exclusively to the sampled items.

COA_02_S.rpt, V 47 printed on 31 Jul 2020 at 11:41:41 Time zone GMT +2 by MY from VALPROD

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Mangelstfeld 4 5, 6
97708 Bad Bocklet
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Ärztlicher Leiter:
PD Dr. med. Andreas Schwarzkopf

Pers. haftende Gesellschafterin:
Labor LS SE Verwaltungsgesellschaft
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USt.-Id. DE 317 022 554
EORI-Nr. DE 924 152 552 472 780

Hypo Vereinsbank Schweinfurt

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Verwaltungsrat (Vors.):
Dipl. Kfm. Werner Wohnhas
Geschäftsführende Direktoren:
Dr. Jürgen Balles, Sabine Fingerhut-Heinemann

BIC HYVEDE33HAN



Ionisation par rayons gamma (gamma irradiation)

Etablissement (factory):

IONISOS

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A l'attention de Samuel LALEVEE

BIOXAL

ZI SUD - SECTEUR A -CITE DES VARENNES

71103 Chalon/Saone Cedex

France

CERTIFICAT DE TRAITEMENT

(Treatment certificate)

Nom du client (Treatment done for)	BIOXAL
Référence article client (Product description)	CLEARKLENS OXIFAST VH49
Référence BL client (your delivery note)	(N° BL= du)
Référence Commande client (your purchase order)	(N° Cde=4500225121 du 12/05/2020)
Numéro de Lot client (your batch)	SEP/1551584/20/147
Quantité de colis (Quantity of boxes)	144
Date de traitement (Treatment date)	26/06/2020
N° de traitement Ionisos (Ionisos treatment number)	20T02387D
N° de commande Ionisos (Ionisos order)	2008178D

RELEVÉ DES DOSES (Observed doses)

Position	Doses lues (Doses controled) kGy / Doses visées (Doses requested) kGy
R	22.80 - 23.00 / 16.20 - 23.20
-	-
-	-
-	-
-	-
-	-

DMM/PC/DUPC version4

Traitement contrôlé par (treatment controlled by) Marion Grampfort

Fait le (date) 29/06/2020

Ce certificat fait l'objet d'une signature électronique (This certificate was signed electronically)

IONISOS est certifié ISO 9001 - ISO 14001 - ISO 11137 - ISO 13485