

Certificate of Analysis

Date 05/03/2020

Article
SKU 100934589 ClearKlens oxifast 1L sterile

page 1/1

batch: SEP/1543188/20/008
expiry date: 2022-01
date of manufacture: 06/01/2020

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	%	3,07	2,90	3,40	Yes
loss TAO 16h at 96°C MAN LCQ 009	%	0,66	0,00	2,50	Yes
Sterility certificate European Pharmacopeia 2.6.1					Yes

released on : 05/03/2020

by : LALEVEE

Comments:

Sterility certificate n° 200210-0065-001

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: 1543188
Quantity: 1152 bottles,

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

Samuel LALEVEE

BIOXAL Quality Manager

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

BIOXAL S.A.
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Cit  des Varennes
71103 CHALON SUR SA NE
FRANKREICH

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labor@labor-ls.de
www.labor-ls.de

Valid  le 05/03/2020



Bad Bocklet 05 Mar 2020 / BB / BIOXCh

Certificate of Analysis

LS No:	200210-0065-001	LS Code:	1521225 / S
Product name:	CLEARKLENS OXIFAST VH49		
Lot No:	SEP/1543188/20/008		
Description:	IONISOS		
Entry temperature:	room temperature		
Your Order No:	4500217755		
Order dated:	13 Jan 2020	Sample receipt:	10 Feb 2020
Start of test:	17 Feb 2020	End of test:	05 Mar 2020

Test for Sterility on "ClearKlens Oxifast VH 49, 8 samples   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 existent for this volume!)	
Reference document:	Growth promotion test (140225-0139-001)	
Test method:	Membrane filtration	
Test environment:	Clean room	
Number of samples tested:	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:		20 Feb 2020
End of incubation:		05 Mar 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 05 Mar 2020 at 11:54 by Stefan G rtner, Head of Department.



Ionisation par rayons gamma (gamma irradiation)

Établissement (factory):

IONISOS

Parc Dombes Côtières Activités

01120 Dagneux - France

Tél : +33 (0)4 78 06 41 14

Fax : +33 (0)4 78 06 06 20

www.ionisos.com

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=4500217755 du 13/01/2020)
Numéro de Lot client (your batch)	
Quantité de colis (Quantity of boxes)	144
Date de traitement (Treatment date)	03/02/2020
N° de traitement Ionisos (Ionisos treatment number)	20T00418D
N° de commande Ionisos (Ionisos order)	2000184D

RELEVÉ DES DOSES (Observed doses)

Position	Doses lues (Doses controled) kGy / Doses visées (Doses requested) kGy
R	17.10 - 17.40 / 16.20 - 23.20
.	-
.	-
.	-
.	-
.	-

DIMMPC/DVPC version4

Les doses sont données avec une incertitude de +/- 5.6 % (Dose measurements shown on the treatment certificate are given with an uncertainty of +/- 5,6 %)

Traitement contrôlé par (treatment controlled by) Stéphanie BERGERON

Fait le (date) 07/02/2020

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