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Bad Bocklet 16 May 2022 / MY / BIOXCh

Certificate of Analysis

LS No:	220429-0210-001	LS Code:	2037933 / S
Product name:	Clearklens Oxifast 1L		
Lot No:	1581341 - SEP/1581341/221060		
Description:	2024/03, IONISOS		
Entry temperature:	Room Temperature		
Your Order No:	4500253241 / 4500251906		
Order dated:	24 Apr 2022	Sample receipt:	29 Apr 2022
Start of test:	02 May 2022	End of test:	16 May 2022

B. Pigeaux
17/06/2022

Sterilprüfung an "ClearKlens Oxifast, 8 Muster à 1 L"

Parameter	Specification / Demands	Result
Test Procedure according to:	Ph Eur 2.6.1 (No product specific suitability test or method transfer for this volume existent!)	
Reference Document:	Wachstumskontrolle (140225-0139-001) an "PERFORM STERILE PAA"	
Test Method:	Membrane Filtration	
Test Environment:	Clean Room	
No. of tested Samples:	8 unit(s)	8 unit(s)
Tested Volume per Sample:	100 ml	100 ml
Sample Dilution:	100 ml Produkt pro Muster in insg. 8 x 600 ml Fluid A vorverdünnen (= 100 ml Produkt/ 600 ml Fluid A)	
Type of Filter Material:	PVDF (Durapore®)	PVDF (Durapore®)
Test System:	TZHLV210 (PVDF)	TZHLV210 (PVDF)
Nutrient Media:	TSB & FTM with neutralization agents (C+/T+)	C+/T+
Volume of Used Media:	100 ml	100 ml
Start of Incubation:		02 May 2022
End of Incubation:		16 May 2022
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 16 May 2022 at 09:36 by Olivia Halamoda, Specialist Manager.

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The determined results refer exclusively to the sampled items.

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Hypo Vereinsbank Schweinfurt

USt-Id.: DE 317 022 554
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