

Diversey Europe BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

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CERTIFICATE OF ANALYSIS

Date: 30 September 2021

Product Name	CLEARKLENS DE VH29				
Product Code	101101081				
Batch Number	FMP21249 52599				
Production Date	06/09/2021				
Expiration Date	EXP 06/09/2023				

This is to certify that the above batch of product has been tested and conforms to the manufacturing Quality Control specification for the product.

Test	Test Method	Lir	nits	Results	
		Lower -	- Upper		
Appearance	Visual	Clear Colou	ırless Liquid	Clear Colourless Liquid	
Specific Gravity (20°C)	DM004	0.880	0.888	0.887	

	Name:	Angelika Partynska 🛮 Justyna Staron
On behalf of Diversey site Quality Manager	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Template	Version: 02	Date of issuing: November 24th 2017



Certificate of Processing

STERIGENICS Seymour Link Road Woodthorpe Mastin Moor TEL FAX www.sterigenics.com

R55480102 09

09/20/2021 10:12:08 GMT

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 2963593 P.O.# 400824 Sales Order # 2863790

25 - 45 kGy Gamma Irradiation Irradiation Date/Time: 09/17/2021 22:45:20 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	704 I	вх	101101081	Diversey Clearklens DE 900ml	FMP21249	52599/STR002096
	Dose Map		302_0112	REF: 13.5A3 AF Min = 0.717		
102.000	21	BX	101101081_SAMPLE	Diversey Clearklens DE 900ml	FMP21249	52599/STR002096
	Dose Map		302_0112	REF: 13.5A3 AF Min = 0.717		
	725 I	вх	Total			

Quality Test Summary

Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	User	 Date /Time
	quanty 100t 2000 ipiloti	пппппппппппп	шахинані ороо	rtooun	r doorr an		Date / Time
450.00	Minimum Dose	25.0 kGy	45.0 kGy	27.5 KGY	Pass	DMARRIOTT	09/20/2021 03:12:50 GMT
		Reason Code Test				DAVID MARRIOTT	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.2 KGY	Pass	ESILLS	09/20/2021 04:47:57 GMT
		Reason Code Test				EMMA SILLS	

Sterigenics certifies that the materials listed above (as described by the Manufacturer) received the indicated doses within the precision and accuracy of the dosimetry system employed.

Electronically Signed By: EMMA SILLS Date: 09/20/2021 06:11:56 GMT

Reason: Work Order Completions

PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

ClearKlens DE

Sample Description:

Sampe Code: Fmp21249 52599

Lucideon Sample Number: UK214111-27770

Lucideon Report Number: UK214111-27770/MFEP

Issue Number:

Date Logged:

29-Sep-2021

Order Number:

400923

Date Reported:

19-Oct-2021

Date(s) of Test(s):

05-Oct-2021 to 19-Oct-2021

Sterility Testing

Membrane Filtration EP

Test Results:

Result: Pass

The test results meet the EP/USP criteria: Yes

Tests carried out in accordance with cGMP

End of Test Report

NCBOOK 19-001-21

Mrs Natalie Boot

Business Support Administrator

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Stoke-on-Trent



PHARMACEUTICAL ANALYSIS REPORT

Description:

Endotoxin Test (EP)

Test Method:

2.6.14 Bacterial Endotoxins - Method C - Turbidmetric Kinetic Method

Lucideon Sample Number:

UK214111-27771

Sample Description:

ClearKiens DE

Lucideon Report Number:

UK214111-27771/PM

Client Reference:

Sample Code: Fmp21249 52599

Issue Number:

4

Client:

Flexible Medical Packaging

Unit 8

Hightown

White Cross Industrial Estate

Lancaster LA1 4XS

For the Attention of:

Mrs.Olga Kirchner

Date Logged:

29-Sep-2021

Date of Tests:

06-Oct-2021

to 14-Oct-2021

Report Date:

19-Oct-2021

Purchase Order No.:

400923

Tests carried out in accordance with cGMP

19-0:17-21

Mr Parmjit S Bilan

Pharmaceutical Business and Technical Manager

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Mrs Natalle Boot Business Support Administrator

This report is issued in accordance with the Conditions of Business of Lucideon Limited and relates only to the sample(s) tested. No responsibility is taken for the scourscy of the sampling unless this is done under our own supervision. This report shall not be reproduced in part without the written approval of Lucideon Limited, nor used in any way as to lead to micropresentation of the results or their implications.

Lucideon Limited Queens Road, Penkhull Stoke-on-Trent Staffordshire ST4 7LQ T +44 (0)1782 764428 enquiries@lucideon.com www.fucideon.com Lucideon Report Reference: UK214111/PM Issue 1

Sample Number:

UK214111-27771

Description:

ClearKlens DE

Customer Reference:

FMP21249 52599

Date(s) of Test(s):

06-Oct-21

Date(s) of Re-test(s): 08-Oct-21 (hypothesis testing) and 14-Oct-21 (re-test)

RESULTS

Endotoxin

Sample Number	Specification (EU/ml)	Result (EU/ml)	Spike Recovery (%)
UK214111-27771 Initial	<0.2	>200.0000	N/A
UK214111-27771 Hypothesis test - LAL pipette (A)	<0.2	<0.2000	76
UK214111-27771 Hypothesis test - LAL pipette (B)	<0.2	<0.2000	103
UK214111-27771 Hypothesis test - LAL pipette (C)	<0.2	<0.2000	87
UK214111-27771 Hypothesis test - not LAL pipette (D)	<0.2	<0.2000	85
UK214111-27771 Hypothesis test - not LAL pipette (E)	<0.2	<0.2000	86
UK214111-27771 Hypothesis test - not LAL pipette (F)	<0.2	<0.2000	126
UK214111-27771 Re-test	<0.2	<0.2000	127

The above testing was carried out in accordance with cGMP. All standards, controls, coefficients of variation and correlation coefficients were satisfactory.

The initial test result does not meet the Ph Eur/USP criteria.

The hypothesis re-test results meet the Ph Eur/USP criteria.

The re-test result meets the Ph Eur/USP criteria.

Refer to Laboratory investigation Report (LIR) 0740.

END OF TEST REPORT