

Diversey Europe Operations BV Maarssenbroeksedijk 2 3542 DN Utrecht The Netherlands

Tel. +31 (0)30 247 6427 www.Diversey.com

CERTIFICATE OF ANALYSIS

Date: 07 April 2020

Product Name	CLEA	ARKLENS IPA VH1	
Product Code	7513400		
Batch Number	FMP20069	49185	
Production Date	09/03/2020		
Expiration Date	EXP 09/03/2022		

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	Limi Lower	ts - Upper	Results	
Appearance	Visual	Clear Colou	ırless Liquid	Clear Colourless Liquid	
Specific Gravity (20°C)	DM004	0.872	0.883	0.877	

On behalf of Diversey site Quality Manger	Name:	urszula Haraburda Angelika Partynski		
	Position	Quality Control Inspector		

This document being issued electronically does not bear a signature

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



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R55480102

03/19/2020 10:40:37 GMT

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Customer Name: P.O.#

FLEXIBLE MED. GBP UK LANCASTER

Total

Processing Facility:

Markham Vale

Work Order # Sales Order #

2629428

2456806

25 - 45 kGy

860

вх

Gamma Irradiation

Irradiation Date/Time:

03/18/2020 17:21:19 GMT

SO Qty UOM **Customer Item Number Customer Item Description** Customer Customer Line # Lot Number Load Number 101.000 860 BX 7513400 Diversey Clearklens IPA 900 mL FMP20069 WO49185/DEV001152 Dose Map 302_0030

Quality Test Summary

-----Signed By ----Op# **Quality Test Description Minimum Spec Maximum Spec** Result Pass/Fail User Date /Time 450.00 Minimum Dose 25.0 kGy 45.0 kGy 27.4 KGY Pass **DMARRIOTT** 03/19/2020 05:29:00 GMT Reason Code Test DAVID MARRIOTT 450.00 Maximum Dose 25.0 kGy 45.0 kGy 40.1 KGY Pass AHORSON 03/19/2020 10:33:11 GMT Reason Code Test **ASHLEY HOBSON**

Ref Pos: 10E1, AF Min = 0.71

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:

ASHLEY HOBSON

Reason:

Work Order Completions

03/19/2020 10:38:36 GMT



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R55480102

03/30/2020 10:27:25 GMT

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Customer Name: P.O.#

FLEXIBLE MED. GBP UK LANCASTER

Processing Facility:

Markham Vale

Work Order # Sales Order # 2633401 2461498

25 - 45 kGy

Gamma Irradiation

Irradiation Date/Time:

03/25/2020 03:28:04 GMT

SO Line #	Qty UON	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	531 BX Dose Map	7513400 302_0030	Diversey Clearklens IPA 900 mL Ref Pos: 10E1, AF Min = 0.71	FMP20069	WO49185/DEV001152
102.000	29 BX Dose Map 560 BX	7513400_SAMPLE 302_0030 Total	Diversey Clearklens IPA 900 mL Ref Pos: 10E1, AF Min = 0.71	FMP20069	WO49185/DEV001152

Quality Test Summary

Ор#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	Signed By User	- Date /Time
450.00	Minimum Dose	25.0 kGy	45.0 kGy	28.2 KGY	Pass	AWAGSTAFF	03/25/2020 21:30:43 GMT
450.00	Maximum Dose	Reason Code Test 25.0 kGy Reason Code Test	45.0 kGy	41.4 KGY	Pass	ADDISON WAGSTAFF AWAGSTAFF ADDISON WAGSTAFF	03/25/2020 21:31:10 GMT

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: ASHLEY HOBSON

Reason: Work Order Completions

Date: 03/30/2020 10:25:52 GMT



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R55480102

04/03/2020 9:36:07 GMT

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Customer Name: P.O.#

FLEXIBLE MED. GBP UK LANCASTER

PO35115

Processing Facility:

Markham Vale

Work Order # Sales Order#

2638660 2467998

25 - 45 kGv

Gamma irradiation

Irradiation Date/Time:

04/01/2020 05:25:03 GMT

80 Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer	Customer
101.000	688	BX	101101081	Bit. and co	Lot Number	Load Number
102,000	Dose Map		302_0030	Diversey Clearklens DE 900ml Ref Pos: 10E1, AF Min = 0,71	FMP20083	WO49600/DEV002096
103.000	Dose Map	BX	101701081_SAMPLE 302_0030 7513400	Diversey Clearkiens DE 900m) Ref Pos: 10E1, AF Min = 0.71	FMP20083	WO49600/DEV002096
	Dose Map 700	BX	302_0030 Total	Diversey Clearkiens iPA 900 mL Ref Pos: 10E1, AF Min = 0.71	FMP20069	WO49185/DEV001152

Quality Test Summary

_			GORRY TOST SUMMARY				
Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Den - 17-11	Signed By	
450.00	Minimum Dose	25.04-0		Longitt	Pass/Fall	User	Date /Time
450.00	Maximum Dose	25.0 kGy Reason Code Test	45.0 kGy	27.2 KGY	Pass	DMARRIOTT DAVID MARRIOTT	04/02/2020 10:18:06 GMT
450.00		25.0 kGy Reason Code Test	45.0 kGy	41.8 KGY	Pass	Allondon	04/02/2020 14:46:13 GMT

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: ASHLEY HOBSON
Reason: Work Order Completions

Date: 04/03/2020 09:33:00 GMT

PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA14XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

Clear Klens IPA

Sample Description:

Sample Code: Fmp20069 49185

Lucideon Sample Number: UK201633-12722

Lucideon Report Number: UK201633-12722/MFEP

Issue Number:

Date Logged:

08-Apr-2020

Order Number:

PO 35190

Date Reported:

04-May-2020

Date(s) of Test(s):

18-Apr-2020 to 02-May-2020

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

Mrs Andrea Saunders

Business Support Assistant

Stoke-on-Trent

PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA1 4XS

FAO:

Mrs.Olga Kirchner

Report of Tests on:

Clear Klens IPA

Sample Description:

Sample Code: Fmp20069 49185

Lucideon Sample Number: UK201633-12723

Lucideon Report Number: UK201633-12723/ETEP

Issue Number:

Date Logged:

08-Apr-2020

Order Number:

PO 35190

Date Reported:

12-May-2020

Date(s) of Test(s):

09-May-2020 to 09-May-2020

Endotoxin Test (EP)

2.6.14 Bacterial Endotoxins - Method C - Turbidimetric Kinetic Method

Test Results:

The test results meet the EP/USP criteria: Yes

Result: Pass (<0.2 EU/ml)

Tests carried out in accordance with cGMP

End of Test Report

Mrs Andrea Saunders

Business Support Assistant

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