

Diversey Europe Operations BV Maarssenbroeksedijk 2 3642 DN Utrecht The Netherlands

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CERTIFICATE OF ANALYSIS

Date:

13 March 2020

Product Name	CLEARKLENS IPA VH1				
Product Code	7513400				
Batch Number	FMP20044	49156			
Production Date	13/02/2020				
Expiration Date	EXP 13/02/2022				

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	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	Name:	urszula Haraburda Angelika Partynska
Quality Manger	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 02/24/2020 11:34:42 GMT

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 2612006 P.O.# PO34782 Sales Order # 2436024

25 - 45 kGy Gamma Irradiation Irradiation Date/Time: 02/21/2020 17:37:32 GMT

SO Line #	Qty UON	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	710 BX	101100418	Diversey Clearklens IPA/DE 900	FMP20041	WO49184/DEV002080
	Dose Map	302_0030	Ref Pos: 10E1, AF Min = 0.71		
102.000	3 BX	101100418_SAMPLE	Diversey Clearklens IPA/DE 900	FMP20041	WO49184/DEV002080
	Dose Map	302_0030	Ref Pos: 10E1, AF Min = 0.71		
103.000	2 BX	101100418	Diversey Clearklens IPA/DE 900	TRIAL	T020/026
	Dose Map	302_0030	Ref Pos: 10E1, AF Min = 0.71		
104.000	165 BX	7513400	Diversey Clearklens IPA 900 mL	FMP20044	WO49156/DEV001152
	Dose Map	302_0030	Ref Pos: 10E1, AF Min = 0.71		
	880 BX	Total			

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	26.9 KGY	Pass	TKVARDA	02/22/2020 05:29:09 GMT
		Reason Code Test				TOMAS KVARDA	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	40.4 KGY	Pass	TKVARDA	02/22/2020 05:29:31 GMT
		Reason Code Test				TOMAS KVARDA	

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: 02/24/2020 11:33:03 GMT

Reason: Work Order Completions



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R55480102

02/28/2020 15:54:04 GMT

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 2616466 P.O.# PO34817 Sales Order # 2441319

25 - 45 kGy Gamma Irradiation Irradiation Date/Time: 02/27/2020 05:27:04 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	860	вх	7513400	Diversey Clearklens IPA 900 mL	FMP20044	WO49156/DEV001152
	Dose Map)	302_0030	Ref Pos: 10E1, AF Min = 0.71		
	860	вх	Total			

Quality Test Summary

						Signea 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	28.0 KGY	Pass	JATKINSON	02/27/2020 23:03:36 GMT
		Reason Code Test				JOE ATKINSON	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	41.6 KGY	Pass	AHOBSON	02/28/2020 15:50:15 GMT
		Reason Code Test				ASHLEY HOBSON	

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 Date: 02/28/2020 15:52:21 GMT

Reason: Work Order Completions



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R55480102

03/09/2020 10:55:40 GMT

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 2620073 P.O.# PO34855 Sales Order # 2445844

25 - 45 kGy Gamma Irradiation Irradiation Date/Time: 03/08/2020 05:08:31 GMT

SO Line #	Qty UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	400 BX	7513400	Diversey Clearklens IPA 900 mL	FMP20044	WO49156/DEV001152
	Dose Map	302_0030	Ref Pos: 10E1, AF Min = 0.71		
102.000	4 BX	7513400_SAMPLE	Diversey Clearklens IPA 900 mL	FMP20044	WO49156/DEV001152
	Dose Map	302_0030	Ref Pos: 10E1, AF Min = 0.71		
103.000	16 BX	FMP Dunnage Boxes	Customer Supplied	NA	T019/167
	Dose Map	302_0030	Ref Pos: 10E1, AF Min = 0.71		
	420 BX	Total			

Quality Test Summary

Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	User	Date /Time
450.00	Minimum Dose	25.0 kGy Reason Code Test	45.0 kGy	27.1 KGY	Pass	MFORD MARTYN FORD	03/08/2020 18:09:12 GMT
450.00	Maximum Dose	25.0 kGy Reason Code Test	45.0 kGy	38.8 KGY	Pass	MFORD MARTYN FORD	03/08/2020 18:09:30 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 Date: 03/09/2020 10:53:59 GMT

Reason: Work Order Completions

PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Unit 8 Hightown White Cross Industrial Estate Lancaster LA1 4XS

Mrs.Olga Kirchner

Report of Tests on:

Clear Klens IPA

Sample Description:

Sample Code: Fmp20044 49156

Lucideon Sample Number: UK201296-10109

Lucideon Report Number: UK201296-10109/MFEP

Issue Number:

1

Date Logged:

16-Mar-2020

Order Number:

PO34979

Date Reported:

06-Apr-2020

Date(s) of Test(s):

21-Mar-2020 to 04-Apr-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

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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: Fmp20044 49156

Lucideon Sample Number: UK201296-10110

Lucideon Report Number: UK201296-10110/ETEP

Issue Number:

1

Date Logged:

16-Mar-2020

Order Number:

PO34979

Date Reported:

Date(s) of Test(s):

26-Mar-2020

Endotoxin Test (EP)

19-Mar-2020 to 19-Mar-2020

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

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Mrs Natalie Boot

Senior Business Support Assistant