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CERTIFICATE OF ANALYSIS

Date: 17.09.2019

Product Name	CLEARKLENS IPA VH1
Product Code	101100418
Batch Number	FMP19191 47716
Production Date	10/07/2019
Expiration Date	EXP 10/07/2021

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	Limits		Results
		Lower	Upper	
Appearance	Visual	Clear Colourless Liquid		clear colourless liquid
Specific Gravity (20°C)	DM004	0.872	0.883	0.877

On behalf of Diversey site Quality Manager	Name :	Karabinda Pantyushe
	Position	Quality Control Inspector

This document being issued electronically does not bear a signature

COA Template	Version : 02	Date of issuing : November 24 th 2017
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R55480102

 09/10/2019 11:32:54 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	2508562
P.O.#	PO33822			Sales Order #	2315500
	25 - 45 kGy	Gamma Irradiation	Irradiation Date/Time:	09/08/2019 07:42:17 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	445	BX	7513400	Diversey Clearkens IPA 900 mL	FMP19178	WO47944 / DEV001152
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
102.000	430	BX	101100418	Diversey Clearkens IPA/DE 900	FMP19191	WO47716 / DEV002080
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
103.000	5	BX	101100418_SAMPLE	Diversey Clearkens IPA/DE 900	FMP19191	WO47716 / DEV002079
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
	880	BX	Total			

Quality Test Summary

Op#	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	27.8 KGY	Pass	ESILLS	09/10/2019 11:29:21 GMT
		Reason Code Test				EMMA SILLS	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	45.1 KGY	Fail	IWEATHERAL	09/09/2019 09:11:00 GMT
		Reason Code Test				IAN WEATHERALL	

The above products were not processed according to the process specification requirements. Some parameters reviewed were found not to be in compliance with specifications as indicated on attached nonconformance document(s).

Please refer to DEF-10122. Maximum dose achieved is over the Customer Specification. Incorrect dosimeter placement during processing run. Minimum dose calculated using ratio factors.

Electronically Signed By: EMMA SILLS
 Reason: Work Order Completions

Date: 09/10/2019 11:32:08 GMT

R55480102

 09/13/2019 9:24:49 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	2511299
P.O.#	PO33633			Sales Order #	2318456
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	09/12/2019 14:29:27 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	278	BX	101100418	Diversey Clearkens IPA/DE 900	FMP191911	WO47716 / DEV002080
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
102.000	703	BX	7515783	Diversey Clearkens DE 900 mL	FMP19203	WO47639 / DEV001333
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
103.000	369	BX	7513400	Diversey Clearkens IPA 900 mL	FMP19213	WO47635 / DEV001152
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
104.000	5	BX	7515783 Sample	Diversey Clearkens DE 900 mL	FMP19203	WO47639 / DEV001333
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
105.000	5	BX	7513400_SAMPLE	Diversey Clearkens IPA 900 mL	FMP19213	WO47635 / DEV001152
	Dose Map		302_0030	Ref Pos: 10E1, AF Min = 0.71		
	1360	BX	Total			

Quality Test Summary

Op#	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	29.2 KGY	Pass	ESILLS	09/13/2019 07:26:38 GMT
		Reason Code Test				EMMA SILLS	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	42.8 KGY	Pass	ESILLS	09/13/2019 07:36:31 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
 Reason: Work Order Completions

Date: 09/13/2019 07:46:53 GMT

PHARMACEUTICAL ANALYSIS REPORT

LUCIDEON

insight creating advantage

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: FMP19191 47716

Lucideon Sample Number: (195132)-39889

Lucideon Report Number: (195132)-39889/MFEP Issue Number: 1

Date Logged: 16-Sep-2019 Order Number: PO 33882

Date Reported: 07-Oct-2019 Date(s) of Test(s): 23-Sep-2019 to 07-Oct-2019

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


07 OCT 19

Mrs Andrea Saunders
Business Support Assistant

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PHARMACEUTICAL ANALYSIS REPORT

LUCIDEON

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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: FMP19191 47716

Lucideon Sample Number: (195132)-39890

Lucideon Report Number: (195132)-39890/ETEP Issue Number: 1

Date Logged: 16-Sep-2019 Order Number: PO 33882

Date Reported: 25-Sep-2019 Date(s) of Test(s): 22-Sep-2019 to 22-Sep-2019

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

N. Boot 25-Sep-19

Mrs Natalie Boot

Senior Business Support Assistant

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