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CERTIFICATE OF ANALYSIS

Date Issue: 20 July 2021

Product Name	DI ClearKlens IPA VH1 S 6x0.9L					
Product Code	⊠101105062/□101105063/□101105064					
Batch Number	FMP21175 52072					
Production date	24/06/2021					
Expiration Date	EXP 24/06/2023					

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	Specification	Unit	Results
Appearance	Visual	Colouriess Clear Liquid	N/A	Colourless Clear Liquid
Specific Gravity (20°C)	DM 004	0.872 - 0.883	g/cm³	0.875

Control of the Sterility of the product:

Test	Test Method	Specification	Conformity	Reference number	
Sterilization	Gamma Irradiation	25.0 - 45.0 (kGy)	Yes	52072	
Sterility certificate	Sterility by Membrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	Yes	UK213134- 21259	
2.6.14 Bacterial Endotoxins	Method C - Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	Yes	UK213134- 21260	



by : 05001

Position: QA ADMIN

The analysis results above could change over time and in function of the storage temperature. It is imperative to store the products according to the recommended conditions indicated in the SDS.

End of certificate of analysis

Pharma COA Template	COA Ph 01	July 2020	Page 1 of 1
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Certificate of Processing

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

R55480102

08/13/2021 10:41:09 GMT

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 2916004 P.O.# Sales Order # 2806512

25 - 45 kGy Gamma Irradiation Irradiation Date/Time: 07/03/2021 08:53:08 GMT

SO Line #	Qty UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
106.000	824 BX	101105062	Diversey Clearklens IPA 900ml	FMP21169	WO52071/STR002199
	Dose Map	302_0112	REF: 13.5A3 AF Min = 0.717		
108.000	3 BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP21169	WO52071/STR002199
	Dose Map	302_0112	REF: 13.5A3 AF Min = 0.717		
109.000	123 BX	101105062	Diversey Clearklens IPA 900ml	FMP21175	WO52072/STR002199
	Dose Map	302_0112	REF: 13.5A3 AF Min = 0.717		
	950 BX	Total			

Quality Test Summary

			quality 10	or ourman,	,	Signed By	-
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	27.0 KGY	Pass	DMARRIOTT DAVID MARRIOTT	07/03/2021 16:56:03 GMT
450.00	Maximum Dose	25.0 kGy Reason Code Test	45.0 kGy	39.1 KGY	Pass	DMARRIOTT DAVID MARRIOTT	07/03/2021 16:56:22 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: EMMA SILLS Date: 08/13/2021 10:40:58 GMT

Reason: Work Order Completions



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07/12/2021 10:25:06 GMT

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 2922102 P.O.# 400206 Sales Order # 2813946

25 - 45 kGy Gamma Irradiation Irradiation Date/Time: 07/09/2021 23:08:47 GMT

so UOM **Customer Item Number Customer Item Description** Customer Qty Customer Line # Lot Number **Load Number** WO52072/STR002199 105.000 950 ВХ 101105062 Diversey Clearklens IPA 900ml FMP21175 Dose Map REF: 13.5A3 AF Min = 0.717 302 0112 вх 950 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	27.3 KGY	Pass	IWEATHERAL	07/10/2021 16:17:10 GMT
		Reason Code Test				IAN WEATHERALL	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.1 KGY	Pass	IWEATHERAL	07/10/2021 16:17:32 GMT
		Reason Code Test				IAN WEATHERALL	

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: 07/12/2021 10:24:53 GMT

Reason: Work Order Completions



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R55480102 07/1

07/12/2021 10:38:50 GMT

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Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 2922104
P.O.# 400209 Sales Order # 2813948

25 - 45 kGy Gamma Irradiation Irradiation Date/Time: 07/09/2021 18:44:31 GMT

SO Line #	Qty UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
103.000	13 BX	7513400_SAMPLE	Diversey Clearklens IPA 900 mL	FMP21175	WO52072/STR002199
	Dose Map	302_0112	REF: 13.5A3 AF Min = 0.717		
107.000	333 BX	101105062	Diversey Clearklens IPA 900ml	FMP21175	WO52072/STR002199
	Dose Map	302_0112	REF: 13.5A3 AF Min = 0.717		
110.000	4 BX	101105062	101105062 Sample	FMP21175	WO52072/STR002199
	Dose Map	302_0112	REF: 13.5A3 AF Min = 0.717		
	350 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	27.7 KGY	Pass	JBARRATT JAMIE BARRATT	07/10/2021 04:39:28 GMT
450.00	Maximum Dose	25.0 kGy Reason Code Test	45.0 kGy	39.0 KGY	Pass	JBARRATT JAMIE BARRATT	07/10/2021 04:39:47 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: EMMA SILLS Date: 07/12/2021 10:38:38 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:

Clear Klens IPA

Sample Description:

Sample Code: Fmp21175 52072

Lucideon Sample Number: UK213134-21260

Lucideon Report Number: UK213134-21260/ETEP

Issue Number:

Date Logged:

20-Jul-2021

Order Number:

PO400364

Date Reported:

10-Aug-2021

Date(s) of Test(s):

04-Aug-2021 to 04-Aug-2021

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: <0.2 EU/ml

Tests carried out in accordance with cGMP

End of Test Report

Mrs Andrea Saunders

Business Support Administrator

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: Fmp21175 52072

Lucideon Sample Number: UK213134-21259

Lucideon Report Number: UK213134-21259/MFEP

Issue Number:

Date Logged:

20-Jul-2021

Order Number:

PO400364

Date Reported:

12-Aug-2021

Date(s) of Test(s):

28-Jul-2021

to 11-Aug-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

Mrs Andrea Saunders

Business Support Administrator

Lucideon Limited

Stoke-on-Trent