

## CERTIFICATE OF ANALYSIS

Date issue: 03 March 2023


<b>Product Name</b>	CLEARLENs IPA VH1		
<b>Product Code</b>	<input type="checkbox"/> 101105062	<input checked="" type="checkbox"/> 101105063	<input type="checkbox"/> 101105064
<b>Batch Number</b>	FMP23039	56143	
<b>Production Date</b>	08/02/2023		
<b>Expiration Date</b>	EXP 08/02/2025		

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	UOM	Results
Appearance	Visual	Clear Colourless Liquid	NA	Clear Colourless Liquid
Specific Gravity (20°C)	DM004	0.872 0.883	g/cm3	0.875

Control of the Sterility of the product:

Test	Test Method	Specification	Conformity	Reference No:
Sterilization	Gamma Irradiation	25.0 - 45.0 (kGy)	YES	56143
Sterility Certificate	Sterility by Mebrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII	No Growth	YES	UK23841-5581
2.6.14 Bacterial Endotoxins	Method C - Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	UK23841-5582

	Date of released on behalf of Diversey's Manufacturing Location:	Testers: Sabcho Svetoslavov	03/03/2023
		Justyna Staron	03/03/2023
		Quality Control Inspector Olga Kirchner	27/03/2023

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\*\*\*

R55480102

02/24/2023 10:54:50 GMT  
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<b>Customer Name:</b>	<b>FLEXIBLE MED. GBP UK LANCASTER</b>	<b>Processing Facility:</b>	<b>Markham Vale</b>	<b>Work Order #</b>	<b>3286742</b>
<b>P.O.#</b>	<b>404554</b>			<b>Sales Order #</b>	<b>3241770</b>
<b>25 - 45 kGy</b>		<b>Gamma Irradiation</b>	<b>Irradiation Date/Time:</b>	<b>02/16/2023 20:51:59 GMT</b>	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	375	BX	101105063	Clearklens IPA 900 mls	FMP23039	WO56143/STR002201
			Dose Map	RF: 13.5A3, AF Min: 0.717		
	<b>375</b>	<b>BX</b>	<b>Total</b>			

**Quality Test Summary**

Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	-----Signed By-----	
						User	Date /Time
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.2 KGY	Pass	BCZAPLA	02/17/2023 13:02:20 GMT
		Reason Code Test				BARTOSZ CZAPLA	
450.00	Minimum Dose	25.0 kGy	45.0 kGy	27.8 KGY	Pass	BCZAPLA	02/17/2023 13:02:35 GMT
		Reason Code Test				BARTOSZ CZAPLA	

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: 02/22/2023 11:10:56 GMT

R55480102

 02/28/2023 8:14:15 GMT  
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<b>Customer Name:</b>	FLEXIBLE MED. GBP UK LANCASTER	<b>Processing Facility:</b>	Markham Vale	<b>Work Order #</b>	3290977
<b>P.O.#</b>	404607			<b>Sales Order #</b>	3246613
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	02/25/2023 14:41:10 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	339	BX	101105063	Clearklens IPA 900 mls	FMP23039	56143/STR002201
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	11	BX	101105063_SAMPLE	Clearklens IPA 900 mls	FMP23039	56143/STR002201
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
	<b>350</b>	<b>BX</b>	<b>Total</b>			

### 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	27.7 KGY	Pass	PSAXTON	02/26/2023 11:29:16 GMT
		Reason Code Test				PAUL SAXTON	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	40.6 KGY	Pass	ESILLS	02/27/2023 09:49:14 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: 02/28/2023 08:14:03 GMT

# PHARMACEUTICAL ANALYSIS REPORT



## Flexible Medical Packaging

Unit 8  
Hightown  
White Cross Industrial Estate  
Lancaster  
LA1 4XS

FAO: Mrs.Olga Kirchner

**Report of Tests on:** ClearKlens IPA

**Sample Description:** Sample Code: Fmp23039 56143

**Lucideon Sample Number:** UK23841-5581

**Lucideon Report Number:** UK23841-5581/MFEP

**Issue Number:** 1

**Date Logged:** 06-Mar-2023

**Order Number:** 404729

**Date Reported:** 27-Mar-2023

**Date(s) of Test(s):** 09-Mar-2023 to 23-Mar-2023

### 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**

*Natalie Boot 27 Mar 23*

Mrs Natalie Boot

**Senior Business Support Administrator**

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# 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:** ClearKlens IPA

**Sample Description:** Sample Code: Fmp23039 56143

**Lucideon Sample Number:** UK23841-5582

**Lucideon Report Number:** UK23841-5582/ETEP

**Issue Number:** 1

**Date Logged:** 06-Mar-2023

**Order Number:** 404729

**Date Reported:** 09-Mar-2023

**Date(s) of Test(s):** 07-Mar-2023 to 07-Mar-2023

### 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 (<0.2000EU/ml)

Tests carried out in accordance with cGMP

**End of Test Report**

NCB001 09 Mar 23

Mrs Natalie Boot

**Senior Business Support Administrator**

Page 1 of 1

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