

## CERTIFICATE OF ANALYSIS

Date issue: 26 March 2024

Product Name	CLEARLENs IPA VH1 S 6x0.9L		
Product Code	<input type="checkbox"/> 101105062	<input checked="" type="checkbox"/> 101105063	<input type="checkbox"/> 101105064
Batch Number	FMP24057	59783	
Production Date	26/02/2024		
Expiration Date	EXP 26/02/2026		

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	0.872

Control of the Sterility of the product:

Test	Test Method	Specification	Conformity	Reference No:
Sterilization	Gamma Irradiation	25.0 - 45.0 (kGy)	YES	59783
Sterility Certificate	Sterility by Membrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	YES	UK241024 - 7264
2.6.14 Bacterial Endotoxins	Method C - Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	UK241024 - 7265

	Date of released on behalf of Diversey's Manufacturing Location:	Testers:	
		Justyna Staron	26/03/2024
		Natalia Traichel	26/03/2024
		Quality Control Inspector	
		Olga Kirchner	22/04/2024

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

03/11/2024 8:45:22 GMT  
Page 1 of 1

<b>Customer Name:</b>	<b>FLEXIBLE MED. GBP UK LANCASTER</b>	<b>Processing Facility:</b>	<b>Markham Vale</b>	<b>Work Order #</b>	<b>3512788</b>
<b>P.O.#</b>	<b>407641</b>			<b>Sales Order #</b>	<b>3505651</b>
	<b>25 - 45 kGy</b>	<b>Gamma Irradiation</b>	<b>Irradiation Date/Time:</b>	<b>03/08/2024 04:26:41 GMT</b>	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	975	BX	101105063	Clearklens IPA 900 mls	FMP24057	59783/STR002201
			Dose Map	RF: 13.5A3, AF Min: 0.717		
	<b>975</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	27.4 KGY	Pass	JATKINSON	03/08/2024 17:27:16 GMT
		Reason Code Test				JOE ATKINSON	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.0 KGY	Pass	JATKINSON	03/08/2024 17:27:45 GMT
		Reason Code Test				JOE ATKINSON	

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: CLAIRE CICALA  
Reason: Work Order Completions

Date: 03/11/2024 08:42:12 GMT

R55480102

03/18/2024 10:33:20 GMT  
Page 1 of 1

<b>Customer Name:</b>	FLEXIBLE MED. GBP UK LANCASTER	<b>Processing Facility:</b>	Markham Vale	<b>Work Order #</b>	3519728
<b>P.O.#</b>	407701			<b>Sales Order #</b>	3513346
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	03/15/2024 15:12:13 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	461	BX	101105063	Clearklens IPA 900 mls	FMP24057	59783/STR002201
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	3	BX	101105063_SAMPLE	Clearklens IPA 900 mls	FMP24057	59783/STR002201
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	381	BX	101105063	Clearklens IPA 900 mls	FMP24067	59785/STR002201
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
104.000	5	BX	101105063_SAMPLE	Clearklens IPA 900 mls	FMP24067	59785/STR002201
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
	850	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	27.6 KGY	Pass	OCUPIT	03/16/2024 04:15:28 GMT
		Reason Code Test				OLIVER CUPIT	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.4 KGY	Pass	OCUPIT	03/16/2024 04:15:56 GMT
		Reason Code Test				OLIVER CUPIT	

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: RHIANNON GATES  
Reason: Work Order Completions

Date: 03/18/2024 10:29:25 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: Fmp24057 59783

**Lucideon Sample Number:** UK241024-7264

**Lucideon Report Number:** UK241024-7264/MFEP **Issue Number:** 1

**Date Logged:** 26-Mar-2024 **Order Number:** 407774

**Date Reported:** 18-Apr-2024 **Date(s) of Test(s):** 29-Mar-2024 to 12-Apr-2024

**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**

DocuSigned by:

*Natalie Boot*

Signer Name: Natalie Boot  
Signing Reason: I have reviewed this document  
Signing Time: 18 April 2024 | 15:29 BST

90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

**Senior Business Support Administrator**

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# 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: Fmp24057 59783

**Lucideon Sample Number:** UK241024-7265

**Lucideon Report Number:** UK241024-7265/ETEP

**Issue Number:** 1

**Date Logged:** 26-Mar-2024

**Order Number:** 407774

**Date Reported:** 19-Apr-2024

**Date(s) of Test(s):** 06-Apr-2024 to 10-Apr-2024

### 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 (<0.2000 EU/ml)

Tests carried out in accordance with cGMP

System suitability failure on initial testing - results invalidated and test repeated with above satisfactory results - see Quality Incident Report (QIR) 12698.

## End of Test Report

DocuSigned by:

*Tracy Wheeler*



Signer Name: Tracy Wheeler

Signing Reason: I have reviewed this document

Signing Time: 19 April 2024 | 15:34 BST

D85AB0246E184F31821E2EC1AFA6CA90

Tracy Wheeler

**Business Support Administrator**

Page 1 of 1

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