

CERTIFICATE OF ANALYSIS

Date issue: 27 January 2025

Product Name	CLEARKLENS IPA VH1 S 6x0.9L		
Product Code	<input checked="" type="checkbox"/> 101105062	<input type="checkbox"/> 101105063	<input type="checkbox"/> 101105064
Batch Number	FMP24352	61266	
Production Date	17/12/2024		
Expiration Date	EXP 17/12/2026		

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	0.875

Control of the Sterility of the product:

Test	Test Method	Specification	Conformity	Reference No:
Sterilization	Gamma Irradiation	25.0 - 45.0 (kGy)	YES	61266
Sterility Certificate	Sterility by Membrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	YES	N25364 - 1/MFEP
2.6.14 Bacterial Endotoxins	Method C - Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	N25364 - 2/ETEP

	Date of released on behalf of Diversey's Manufacturing Location:	Testers:	
		Kyle Ashton	27/01/2025
		Sabcho Svetoslavov	27/01/2025
		Quality Control Inspector	
		Olga Kirchner	18/02/2025

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

01/06/2025 13:46:25 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3679569
P.O.#	409646			Sales Order #	3706522
	25 - 45 kGy	Gamma Irradiation	Irradiation Date/Time:		01/04/2025 02:50:04 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	911	BX	101105062	Diversey Clearklens IPA 900ml	FMP24352	61266/STR002199
		Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	161	BX	101105063	Clearklens IPA 900 mls	FMP24345	61137/STR002201
		Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	3	BX	101105063_SAMPLE	Clearklens IPA 900 mls	FMP24345	61137/STR002201
		Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
	1075	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	27.3 KGY	Pass	JATKINSON	01/05/2025 00:26:39 GMT
		Reason Code Test				JOE ATKINSON	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	38.7 KGY	Pass	JATKINSON	01/05/2025 00:27:03 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-MAESTRE
Reason: Work Order Completions

Date: 01/06/2025 13:43:51 GMT

R55480102

01/13/2025 11:01:24 GMT
Page 1 of 1

Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3685424
P.O.#	409681			Sales Order #	3715208
	25 - 45 kGy	Gamma Irradiation	Irradiation Date/Time:		01/11/2025 12:05:59 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	1075	BX	101105062	Diversey Clearklens IPA 900ml	FMP24352	61266/STR002199
			Dose Map	RF: 13.5A3, AF Min: 0.717		
	1075	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	27.7 KGY	Pass	EMORRIS	01/12/2025 04:18:00 GMT
		Reason Code Test				EDWARD MORRIS	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.2 KGY	Pass	EMORRIS	01/12/2025 04:18:14 GMT
		Reason Code Test				EDWARD MORRIS	

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-MAESTRE**
Reason: **Work Order Completions**

Date: **01/13/2025 11:00:11 GMT**

R55480102

01/20/2025 10:08:30 GMT
Page 1 of 1

Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3688981
P.O.#	409741			Sales Order #	3719188
	25 - 45 kGy	Gamma Irradiation	Irradiation Date/Time:		01/17/2025 08:38:05 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	704	BX	100862174	Diversey Clearklens DE 900 mL	FMP25006	61324/STR001910
		Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	27	BX	100862174 Sample	Diversey Clearklens DE 900 mL	FMP25006	61324/STR001910
		Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	166	BX	101105062	Diversey Clearklens IPA 900ml	FMP24352	61266/STR002199
		Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
104.000	3	BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP24352	61266/STR002199
		Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
	900	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	27.9 KGY	Pass	OCUPIT	01/18/2025 03:50:40 GMT
		Reason Code Test				OLIVER CUPIT	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	40.0 KGY	Pass	OCUPIT	01/18/2025 03:50:54 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: **CLAIRE CICALA-MAESTRE**
Reason: **Work Order Completions**

Date: **01/20/2025 10:07:45 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: Fmp24352 61266

Lucideon Sample Number: N25364 - 1

Lucideon Report Number: N25364 - 1/MFEP

Issue Number: 1

Date Logged: 28-Jan-2025

Order Number: 409885

Date Reported: 17-Feb-2025

Date(s) of Test(s): 29-Jan-2025 to 12-Feb-2025

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

Signed by:

Natalie Boot



Signer Name: Natalie Boot
Signing Reason: I have reviewed this document
Signing Time: 17 February 2025 | 11:16 GMT

90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

Senior Business Support Administrator

Page 1 of 1

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Certificate Of Completion

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Status: Completed

Subject: N25364 - 1

Source Envelope:

Document Pages: 1

Signatures: 1

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Natalie Boot

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IP Address: 86.188.222.148

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Natalie Boot

natalie.boot@uk.lucideon.com

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Sent: 17-Feb-25 | 11:15

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Status

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Status

Timestamp

Witness Events

Signature

Timestamp

Notary Events

Signature

Timestamp

Envelope Summary Events

Status

Timestamps

Envelope Sent

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17-Feb-25 | 11:15

Certified Delivered

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17-Feb-25 | 11:15

Signing Complete

Security Checked

17-Feb-25 | 11:16

Completed

Security Checked

17-Feb-25 | 11:16

Payment Events

Status

Timestamps

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: Fmp24352 61266

Lucideon Sample Number: N25364 - 2

Lucideon Report Number: N25364 - 2/ETEP

Issue Number: 1

Date Logged: 28-Jan-2025

Order Number: 409885

Date Reported: 04-Feb-2025

Date(s) of Test(s): 30-Jan-2025 to 30-Jan-2025

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

End of Test Report

Signed by:

Natalie Boot



Signer Name: Natalie Boot

Signing Reason: I have reviewed this document

Signing Time: 04 February 2025 | 11:49 GMT

90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

Senior Business Support Administrator

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Certificate Of Completion

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Status: Completed

Subject: sign

Source Envelope:

Document Pages: 1

Signatures: 1

Envelope Originator:

Certificate Pages: 1

Initials: 0

Natalie Boot

AutoNav: Enabled

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Sent: 04-Feb-25 | 11:49

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Timestamps

Envelope Sent

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04-Feb-25 | 11:49

Certified Delivered

Security Checked

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Signing Complete

Security Checked

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Security Checked

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