

CERTIFICATE OF ANALYSIS

Date issue: 24 February 2025


Product Name	CLEARKLENS IPA VH1 S 6x0.9L		
Product Code	<input type="checkbox"/> 101105062	<input checked="" type="checkbox"/> 101105063	<input type="checkbox"/> 101105064
Batch Number	FMP25035	61585	
Production Date	04/02/2025		
Expiration Date	EXP 04/02/2027		

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	61585
Sterility Certificate	Sterility by Membrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	YES	N25819 - 1
2.6.14 Bacterial Endotoxins	Method C - Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	N25819 - 2

	Date of released on behalf of Diversey's Manufacturing Location:	Testers: Natalia Traichel	24/02/2025
		Angelika Pietraszko	24/02/2025
		Quality Control Inspector Olga Kirchner	21/03/2025

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

02/17/2025 13:03:21 GMT
Page 1 of 1

Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3703418
P.O.#	409970			Sales Order #	3736103
	25 - 45 kGy	Gamma Irradiation	Irradiation Date/Time:		02/14/2025 19:27:33 GMT

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	FMP25035/STR002201	61585
			Dose Map	RF: 13.5A3, AF Min: 0.717		
	975	BX	Total			

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	41.1 KGY	Pass	DYATES	02/15/2025 17:46:56 GMT
		Reason Code Test				DANIEL YATES	
450.00	Minimum Dose	25.0 kGy	45.0 kGy	28.1 KGY	Pass	DYATES	02/15/2025 17:47:07 GMT
		Reason Code Test				DANIEL YATES	

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: **02/17/2025 13:01:44 GMT**

Certificate of Processing

STERIGENICS Seymour Link Road Woodthorpe Mastin Moor
TEL (0)1246 561230 FAX www.sterigenics.com

R55480102

02/17/2025 14:23:07 GMT
Page 1 of 1

Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 3708091
P.O.# 410001 Sales Order # 3741247
25 - 45 kGy Gamma Irradiation Irradiation Date/Time: 02/15/2025 00:17:55 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	457	BX	101105063	Clearklens IPA 900 mls	FMP25035	61585/STR002201
		Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	3	BX	101105063_SAMPLE	Clearklens IPA 900 mls	FMP25035	61585/STR002201
		Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	190	EA	302_0112_SAMPLE	Flexible Sample Product	NA	61680/STR002240
		Dose Map	302_0112	RF: 13.5A3, AF Min: 0.717		
	650	EA	Total			

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	39.6 KGY	Pass	DYATES	02/15/2025 17:45:50 GMT
		Reason Code Test				DANIEL YATES	
450.00	Minimum Dose	25.0 kGy	45.0 kGy	28.0 KGY	Pass	DYATES	02/15/2025 17:46:02 GMT
		Reason Code Test				DANIEL YATES	

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: 02/17/2025 14:22:48 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: Fmp25035 61585

Lucideon Sample Number: N25819 - 2

Lucideon Report Number: N25819 - 2/ETEP

Issue Number: 1

Date Logged: 25-Feb-2025

Order Number: 410099

Date Reported: 11-Mar-2025

Date(s) of Test(s): 10-Mar-2025 to 10-Mar-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:

Tracy Wheeler

Signer Name: Tracy Wheeler

Signing Reason: I have reviewed this document

Signing Time: 11 March 2025 | 16:28 GMT

D85AB0246E184F31821E2EC1AFA6CA90

Tracy Wheeler

Business Support Administrator

Page 1 of 1

Certificate Of Completion

Envelope Id: A880CC7B-A1A7-41F8-860F-6D2B09299B6F

Status: Completed

Subject: N25819 sign

Source Envelope:

Document Pages: 1

Signatures: 1

Envelope Originator:

Certificate Pages: 1

Initials: 0

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Envelopeld Stamping: Disabled

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Time Zone: (UTC) Dublin, Edinburgh, Lisbon, London

Tracy.Wheeler@uk.lucideon.com

IP Address: 86.188.245.148

Record Tracking

Status: Original

Holder: Tracy Wheeler

Location: DocuSign

11-Mar-25 | 16:27

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Signer Events

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tracy.wheeler@uk.lucideon.com

Viewed: 11-Mar-25 | 16:28

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Signed: 11-Mar-25 | 16:28

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Signature Adoption: Pre-selected Style

Security Level: Email, Account Authentication (Required), Authentication, Login with SSO

Signature ID:

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Using IP Address: 86.188.245.148

With Signing Authentication via Docusign password

With Signing Reasons (on each tab):

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Electronic Record and Signature Disclosure:

Not Offered via Docusign

In Person Signer Events

Signature

Timestamp

Editor Delivery Events

Status

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Agent Delivery Events

Status

Timestamp

Intermediary Delivery Events

Status

Timestamp

Certified Delivery Events

Status

Timestamp

Carbon Copy Events

Status

Timestamp

Witness Events

Signature

Timestamp

Notary Events

Signature

Timestamp

Envelope Summary Events

Status

Timestamps

Envelope Sent

Hashed/Encrypted

11-Mar-25 | 16:28

Certified Delivered

Security Checked

11-Mar-25 | 16:28

Signing Complete

Security Checked

11-Mar-25 | 16:28

Completed

Security Checked

11-Mar-25 | 16:28

Payment Events

Status

Timestamps

PHARMACEUTICAL ANALYSIS REPORT

Flexible Medical Packaging

Unit 8
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White Cross Industrial Estate
Lancaster
LA1 4XS

FAO: Mrs. Olga Kirchner

Report of Tests on: ClearKlens IPA

Sample Description: Sample Code: Fmp25035 61585

Lucideon Sample Number: N25819 - 1

Lucideon Report Number: N25819 - 1/MFEP

Issue Number: 1

Date Logged: 25-Feb-2025

Order Number: 410099

Date Reported: 20-Mar-2025

Date(s) of Test(s): 26-Feb-2025 to 12-Mar-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:

Tracy Wheeler

Signer Name: Tracy Wheeler

Signing Reason: I have reviewed this document

Signing Time: 20 March 2025 | 15:22 GMT

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Tracy Wheeler

Business Support Administrator

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Certificate Of Completion

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Status: Completed

Subject: N25819 Sign

Source Envelope:

Document Pages: 1

Signatures: 1

Envelope Originator:

Certificate Pages: 1

Initials: 0

Tracy Wheeler

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Queens Road

Envelopeld Stamping: Disabled

Stoke-on-Trent, Staffordshire ST4 7LQ

Time Zone: (UTC) Dublin, Edinburgh, Lisbon, London

Tracy.Wheeler@uk.lucideon.com

IP Address: 86.188.222.148

Record Tracking

Status: Original

Holder: Tracy Wheeler

Location: DocuSign

20-Mar-25 | 15:21

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Signer Events

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Tracy Wheeler

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tracy.wheeler@uk.lucideon.com

Viewed: 20-Mar-25 | 15:22

Placeholder

Signed: 20-Mar-25 | 15:22

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Signature Adoption: Pre-selected Style

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Signature

Timestamp

Notary Events

Signature

Timestamp

Envelope Summary Events

Status

Timestamps

Envelope Sent

Hashed/Encrypted

20-Mar-25 | 15:22

Certified Delivered

Security Checked

20-Mar-25 | 15:22

Signing Complete

Security Checked

20-Mar-25 | 15:22

Completed

Security Checked

20-Mar-25 | 15:22

Payment Events

Status

Timestamps