

CERTIFICATE OF ANALYSIS

Date issue: 05 November 2024


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	FMP24291	60849	
Production Date	17/10/2024		
Expiration Date	EXP 17/10/2026		

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	60849
Sterility Certificate	Sterility by Membrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	YES	UK243744-25436
2.6.14 Bacterial Endotoxins	Method C - Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	UK243744-25437

	Date of released on behalf of Diversey's Manufacturing Location:	Testers:	
		Natalia Traichel	05/11/2024
		Justyna Staron	05/11/2024
		Quality Control Inspector	
		Caroline Pascoe	02/12/2024

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

Certificate of Processing

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

R55480102

10/28/2024 10:26:24 GMT
Page 1 of 1

Customer Name: FLEXIBLE MED. GBP UK LANCASTER Processing Facility: Markham Vale Work Order # 3646884
P.O.# 409283 Sales Order # 3666994
25 - 45 kGy Gamma Irradiation Irradiation Date/Time: 10/26/2024 07:07:43 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	459	BX	101105063	Clearklens IPA 900 mls	FMP24291	60849/STR002201
			Dose Map 302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	16	BX	101105063_SAMPLE	Clearklens IPA 900 mls	FMP24291	60849/STR002201
			Dose Map 302_0112	RF: 13.5A3, AF Min: 0.717		
	475	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	39.1 KGY	Pass	JBARRATT	10/27/2024 04:17:59 GMT
		Reason Code Test				JAMIE BARRATT	
450.00	Minimum Dose	25.0 kGy	45.0 kGy	27.7 KGY	Pass	JBARRATT	10/27/2024 04:18:18 GMT
		Reason Code Test				JAMIE BARRATT	

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: 10/28/2024 10:25:16 GMT

R55480102

11/05/2024 11:07:59 GMT
Page 1 of 1

Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3647767
P.O.#	609284			Sales Order #	3668032
	25 - 45 kGy	Gamma Irradiation	Irradiation Date/Time:		11/03/2024 07:51:06 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	FMP24291	60849/STR002201
			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	39.6 KGY	Pass	CBRITTON	11/04/2024 09:20:14 GMT
		Reason Code Test				CALLUM BRITTON	
450.00	Minimum Dose	25.0 kGy	45.0 kGy	27.6 KGY	Pass	CBRITTON	11/04/2024 09:20:35 GMT
		Reason Code Test				CALLUM BRITTON	

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: **11/05/2024 11:04:48 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: FMP24291 60849

Lucideon Sample Number: UK243744-25436

Lucideon Report Number: UK243744-25436/MFEP **Issue Number:** 1

Date Logged: 06-Nov-2024 **Order Number:** 409356

Date Reported: 29-Nov-2024 **Date(s) of Test(s):** 09-Nov-2024 to 23-Nov-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

Signed by:

Natalie Boot



Signer Name: Natalie Boot
Signing Reason: I have reviewed this document
Signing Time: 29 November 2024 | 15:24 GMT

90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

Senior Business Support Administrator

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Lucideon Limited T +44 (0)1785 331874
Stone Business Park query@lucideon.com
Brooms Road, Stone www.lucideon.com
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Source Envelope:

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Initials: 0

Natalie Boot

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

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Signature Adoption: Pre-selected Style

Signature ID:

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Status

Timestamp

Witness Events

Signature

Timestamp

Notary Events

Signature

Timestamp

Envelope Summary Events

Status

Timestamps

Envelope Sent

Hashed/Encrypted

29-Nov-24 | 15:23

Certified Delivered

Security Checked

29-Nov-24 | 15:24

Signing Complete

Security Checked

29-Nov-24 | 15:24

Completed

Security Checked

29-Nov-24 | 15:24

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: FMP24291 60849

Lucideon Sample Number: UK243744-25437

Lucideon Report Number: UK243744-25437/ETEP **Issue Number:** 1

Date Logged: 06-Nov-2024 **Order Number:** 409356

Date Reported: 14-Nov-2024 **Date(s) of Test(s):** 08-Nov-2024 to 12-Nov-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

End of Test Report

Signed by:

Natalie Boot



Signer Name: Natalie Boot
Signing Reason: I have reviewed this document
Signing Time: 14 November 2024 | 14:56 GMT

90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

Senior Business Support Administrator

Page 1 of 1

Certificate Of Completion

Envelope Id: 171FAE392C8248E3A7538830914BE0BD
 Subject: SIGN
 Source Envelope:
 Document Pages: 1
 Certificate Pages: 1
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 Envelopeld Stamping: Disabled
 Time Zone: (UTC) Dublin, Edinburgh, Lisbon, London

Status: Completed
 Envelope Originator:
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 Queens Road
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 Natalie.Boot@uk.lucideon.com
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 Security Level: Email, Account Authentication
 (Required), Authentication, Login with SSO

Signature

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 Signature Adoption: Pre-selected Style
 Signature ID:
 90369E90-4813-4123-B65D-5E8FBD375BF3
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Timestamp

Sent: 14-Nov-24 | 14:55
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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

Event	Status	Timestamp
Envelope Sent	Hashed/Encrypted	14-Nov-24 14:55
Certified Delivered	Security Checked	14-Nov-24 14:55
Signing Complete	Security Checked	14-Nov-24 14:56
Completed	Security Checked	14-Nov-24 14:56

Payment Events

Status

Timestamps