

CERTIFICATE OF ANALYSIS

Date issue: 13 March 2024

Product Name	CLEARLENs IPA VH1 S 6x0.9L		
Product Code	☐ 101105062	☒ 101105063	☐ 101105064
Batch Number	FMP24029	59415	
Production Date	29/01/2024		
Expiration Date	EXP 29/01/2026		

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	59415
Sterility Certificate	Sterility by Membrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	YES	UK24612 - 4176
2.6.14 Bacterial Endotoxins	Method C - Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	UK24612 - 4177

	Date of released on behalf of Diversey's Manufacturing Location:	Testers:	
		Angelika Pietraszko	21/02/2024
		Justyna Staron	21/02/2024
		Quality Control Inspector	
		Olga Kirchner	13/03/2024

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

02/12/2024 11:14:18 GMT
Page 1 of 1

Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3496084
P.O.#	407443			Sales Order #	3486377
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	02/09/2024 19:47:24 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	710	BX	101105063	Clearklens IPA 900 mls	FMP24029	59415/STR002201
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	15	BX	101105063_SAMPLE	Clearklens IPA 900 mls	FMP24029	59415/STR002201
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
	725	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	28.1 KGY	Pass	PSAXTON	02/10/2024 20:38:13 GMT
		Reason Code Test				PAUL SAXTON	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	40.4 KGY	Pass	PSAXTON	02/10/2024 20:38:35 GMT
		Reason Code Test				PAUL SAXTON	

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: 02/12/2024 11:05:30 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: Fmp24029 59415

Lucideon Sample Number: UK24612-4176

Lucideon Report Number: UK24612-4176/MFEP **Issue Number:** 1

Date Logged: 20-Feb-2024 **Order Number:** 407551

Date Reported: 12-Mar-2024 **Date(s) of Test(s):** 23-Feb-2024 to 08-Mar-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: 12 March 2024 | 14:52 GMT

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: Fmp24029 59415

Lucideon Sample Number: UK24612-4177

Lucideon Report Number: UK24612-4177/ETEP **Issue Number:** 1

Date Logged: 20-Feb-2024 **Order Number:** 407551

Date Reported: 29-Feb-2024 **Date(s) of Test(s):** 21-Feb-2024 to 21-Feb-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

DocuSigned by:

Natalie Boot



Signer Name: Natalie Boot
Signing Reason: I have reviewed this document
Signing Time: 29 February 2024 | 14:31 GMT

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Mrs Natalie Boot

Senior Business Support Administrator

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