

CERTIFICATE OF ANALYSIS

Date issue: 21 February 2023


Product Name	CLEARLENs IPA VH1		
Product Code	<input type="checkbox"/> 101105062	<input checked="" type="checkbox"/> 101105063	<input type="checkbox"/> 101105064
Batch Number	FMP23011	56137	
Production Date	11/01/2023		
Expiration Date	EXP 11/01/2025		

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	0.877

Control of the Sterility of the product:

Test	Test Method	Specification	Conformity	Reference No:
Sterilization	Gamma Irradiation	25.0 - 45.0 (kGy)	YES	56137
Sterility Certificate	Sterility by Mebrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII	No Growth	YES	UK23639-4287
2.6.14 Bacterial Endotoxins	Method C - Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	UK23639-4288

	Date of released on behalf of Diversey's Manufacturing Location:	Testers:	
		Justyna Staron	21/02/2023
		Sabcho Svetoslavov	21/02/2023
		Quality Control Inspector	
		Olga Kirchner	15/03/2023

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

 01/23/2023 9:42:08 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3271244
P.O.#	404305			Sales Order #	3223927
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	01/19/2023 21:48:43 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	558	BX	101105063	Clearklens IPA 900 mls	FMP23003	56136/STR002201
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	3	BX	101105063_SAMPLE	Clearklens IPA 900 mls	FMP23003	56136/STR002201
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	264	BX	101105063	Clearklens IPA 900 mls	FMP23011	56137/STR002201
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
	825	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	27.5 KGY	Pass	PHAMPSON	01/20/2023 10:29:56 GMT
		Reason Code Test				PIERS HAMPSON	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.1 KGY	Pass	PHAMPSON	01/20/2023 10:30:15 GMT
		Reason Code Test				PIERS HAMPSON	

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: EMMA SILLS
 Reason: Work Order Completions

Date: 01/23/2023 09:41:57 GMT

R55480102

 02/13/2023 9:40:22 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3282917
P.O.#	404496			Sales Order #	3237667
	25 - 45 kGy	Gamma Irradiation		Irradiation Date/Time:	02/11/2023 09:46:33 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	875	BX	101105063	Clearklens IPA 900 mls	FMP23011	56137/STR002201
			Dose Map	RF: 13.5A3, AF Min: 0.717		
	875	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	PSAXTON	02/12/2023 06:05:48 GMT
		Reason Code Test				PAUL SAXTON	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	38.9 KGY	Pass	PSAXTON	02/12/2023 06:06:04 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: EMMA SILLS
 Reason: Work Order Completions

Date: 02/13/2023 09:40:10 GMT

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 02/13/2023 9:38:35 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3284021
P.O.#	404507			Sales Order #	3238852
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	02/11/2023 05:26:53 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	292	BX	101105063	Clearklens IPA 900 mls	FMP23011	56137/STR002201
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	3	BX	101105063_SAMPLE	Clearklens IPA 900 mls	FMP23011	56137/STR002201
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	555	BX	101105063	Clearklens IPA 900 mls	FMP23033	56436/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	28.0 KGY	Pass	PSAXTON	02/12/2023 06:08:05 GMT
		Reason Code Test				PAUL SAXTON	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.6 KGY	Pass	PSAXTON	02/12/2023 06:08:23 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: EMMA SILLS
 Reason: Work Order Completions

Date: 02/13/2023 09:38:23 GMT

PHARMACEUTICAL ANALYSIS REPORT

LUCIDEON

insight creating advantage

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: Fmp23011 56137

Lucideon Sample Number: UK23639-4287

Lucideon Report Number: UK23639-4287/MFEP

Issue Number: 1

Date Logged: 21-Feb-2023

Order Number: 404616

Date Reported: 14-Mar-2023

Date(s) of Test(s): 24-Feb-2023 to 10-Mar-2023

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

NB Boot 14 MAR 23

Mrs Natalie Boot

Senior Business Support Administrator

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PHARMACEUTICAL ANALYSIS REPORT

LUCIDEON

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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: Fmp23011 56137

Lucideon Sample Number: UK23639-4288

Lucideon Report Number: UK23639-4288/ETEP

Issue Number: 1

Date Logged: 21-Feb-2023

Order Number: 404616

Date Reported: 28-Feb-2023

Date(s) of Test(s): 22-Feb-2023 to 22-Feb-2023

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

NcBook 28 Feb 23

Mrs Natalie Boot

Senior Business Support Administrator

Page 1 of 1

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