

CERTIFICATE OF ANALYSIS

Date issue: 16 November 2022


Product Name	CLEARLENs IPA VH1		
Product Code	<input type="checkbox"/> 101105062	<input checked="" type="checkbox"/> 101105063	<input type="checkbox"/> 101105064
Batch Number	FMP22297	55946	
Production Date	24/10/2022		
Expiration Date	EXP 24/10/2024		

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	55946
Sterility Certificate	Sterility by Membrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	YES	UK224527-29561
2.6.14 Bacterial Endotoxins	Method C - Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	UK224527-29562

	Date of released on behalf of Diversey's Manufacturing Location:	Testers:	
		Justyna Staron	16/11/2022
		Sabcho Svetoslavov	16/11/2022
		Quality Control Inspector	
		Olga Kirchner	20/12/2022

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

 11/07/2022 8:40:09 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3227106
P.O.#	403801			Sales Order #	3171125
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	11/05/2022 17:25:56 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	709	BX	101105062	Diversey Clearklens IPA 900ml	FMP22277	55571/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	3	BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP22277	55571/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	238	BX	101105063	Clearklens IPA 900 mls	FMP22297	55946/STR002201
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
	950	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	27.8 KGY	Pass	PHAMPSON	11/06/2022 05:38:25 GMT
		Reason Code Test				PIERS HAMPSON	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.6 KGY	Pass	PHAMPSON	11/06/2022 05:38:46 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: 11/07/2022 08:39:57 GMT

R55480102

 11/14/2022 11:20:08 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3229186
P.O.#	403876			Sales Order #	3173861
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	11/12/2022 03:26:00 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	422	BX	101105062	Diversey Clearklens IPA 900ml	FMP22306	55929/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	475	BX	101105063	Clearklens IPA 900 mls	FMP22297	55946/STR002201
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	3	BX	101105063_SAMPLE	Clearklens IPA 900 mls	FMP22297	55946/STR002201
	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	27.6 KGY	Pass	MFORD	11/12/2022 15:34:08 GMT
		Reason Code Test				MARTYN FORD	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.0 KGY	Pass	CCICALA	11/14/2022 10:05:14 GMT
		Reason Code Test				CLAIRE CICALA	

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
 Reason: Work Order Completions

Date: 11/14/2022 11:19:50 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: Fmp22297 55946

Lucideon Sample Number: UK224527-29561

Lucideon Report Number: UK224527-29561/MFEP **Issue Number:** 1

Date Logged: 17-Nov-2022 **Order Number:** 403970

Date Reported: 20-Dec-2022 **Date(s) of Test(s):** 06-Dec-2022 to 20-Dec-2022

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 20-Dec-22

Mrs Natalie Boot

Senior Business Support Administrator

Page 1 of 1

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PHARMACEUTICAL ANALYSIS REPORT

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Unit 8
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White Cross Industrial Estate
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LA1 4XS

FAO: Mrs.Olga Kirchner

Report of Tests on: ClearKlens IPA

Sample Description: Sample Code: Fmp22297 55946

Lucideon Sample Number: UK224527-29562

Lucideon Report Number: UK224527-29562/ETEP **Issue Number:** 1

Date Logged: 17-Nov-2022 **Order Number:** 403970

Date Reported: 30-Nov-2022 **Date(s) of Test(s):** 20-Nov-2022 to 20-Nov-2022

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


30 Nov 22
Miss Rosie Jones

Pharmaceutical Microbiology Manager

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