

CERTIFICATE OF ANALYSIS

Date issue: 04 November 2022


Product Name	CLEARLENs IPA VH1		
Product Code	<input checked="" type="checkbox"/> 101105062	<input type="checkbox"/> 101105063	<input type="checkbox"/> 101105064
Batch Number	FMP22270	55570	
Production Date	27/09/2022		
Expiration Date	EXP 27/09/2024		

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	N/A	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	55570
Sterility Certificate	Sterility by Membrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	YES	UK224304-28004
2.6.14 Bacterial Endotoxins	Method C - Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	UK224304-28005

	Date of released on behalf of Diversey's Manufacturing Location:	Testers:	
		Angelika Partynska	04/11/2022
		Urszula Haraburda	04/11/2022
		Quality Control Inspector	
		Olga Kirchner	30/11/2022

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

10/10/2022 9:28:46 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3207097
P.O.#	403522			Sales Order #	3147342
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	10/09/2022 03:15:52 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	384	BX	101101081	Diversey Clearklens DE 900ml	FMP22265	55569/STR002096
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	3	BX	101101081_SAMPLE	Diversey Clearklens DE 900ml	FMP22265	55569/STR002096
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	538	BX	101105062	Diversey Clearklens IPA 900ml	FMP22270	55570/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
	925	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	26.7 KGY	Pass	PSAXTON	10/09/2022 16:45:26 GMT
		Reason Code Test				PAUL SAXTON	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	38.1 KGY	Pass	PSAXTON	10/09/2022 16:45:50 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: CLAIRE CICALA
 Reason: Work Order Completions

Date: 10/10/2022 09:28:21 GMT

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10/10/2022 9:28:55 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3207897
P.O.#	403541			Sales Order #	3148407
	25 - 45 kGy	Gamma Irradiation	Irradiation Date/Time:	10/09/2022 06:53:51 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	675	BX	101105062	Diversey Clearklens IPA 900ml	FMP22270	55570/STR002199
			Dose Map	302_0112		
	675	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	26.5 KGY	Pass	PSAXTON	10/09/2022 16:43:10 GMT
		Reason Code Test				PAUL SAXTON	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	38.3 KGY	Pass	PSAXTON	10/09/2022 16:43:31 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: CLAIRES CICALA
Reason: Work Order Completions

Date: 10/10/2022 09:27:55 GMT

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 10/31/2022 11:46:29 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3218848
P.O.#	403697			Sales Order #	3161321
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	10/28/2022 18:57:31 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	225	BX	101105062	Diversey Clearklens IPA 900ml	FMP22270	55570/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	3	BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP22270	55570/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	722	BX	101105062	Diversey Clearklens IPA 900ml	FMP22277	55571/STR002199
	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	27.7 KGY	Pass	DMATHIAS	10/29/2022 04:59:11 GMT
		Reason Code Test				DAVID MATHIAS	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.6 KGY	Pass	ESILLS	10/31/2022 09:43:53 GMT
		Reason Code Test				EMMA SILLS	

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: 10/31/2022 11:38:55 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: Fmp22270 55570

Lucideon Sample Number: UK224304-28004

Lucideon Report Number: UK224304-28004/MFEP **Issue Number:** 1

Date Logged: 04-Nov-2022 **Order Number:** 403875

Date Reported: 25-Nov-2022 **Date(s) of Test(s):** 10-Nov-2022 to 24-Nov-2022

Sterility Testing

Membrane Filtration EP

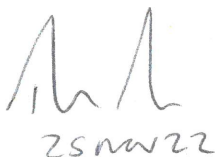
Test Results:

Result: Pass

The test results meet the EP/USP criteria: Yes

Tests carried out in accordance with cGMP

End of Test Report



25 Nov 22

Miss Rosie Jones

Pharmaceutical Microbiology Manager

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Lucideon Limited
Queens Road, Penkhull
Stoke-on-Trent
Staffordshire ST4 7LQ

T +44 (0)1782 764428
enquiries@lucideon.com
www.lucideon.com

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: Fmp22270 55570

Lucideon Sample Number: UK224304-28005

Lucideon Report Number: UK224304-28005/ETEP **Issue Number:** 1

Date Logged: 04-Nov-2022 **Order Number:** 403875

Date Reported: 30-Nov-2022 **Date(s) of Test(s):** 12-Nov-2022 to 12-Nov-2022

Endotoxin Test (EP)

2.6.14 Bacterial Endotoxins - Method C - Turbidimetric Kinetic Method

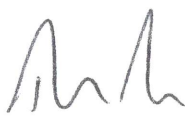
Test Results:

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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Lucideon Limited
Queens Road, Penkhull
Stoke-on-Trent
Staffordshire ST4 7LQ

T +44 (0)1782 764428
enquiries@lucideon.com
www.lucideon.com