

CERTIFICATE OF ANALYSIS

Date issue: 07 September 2023


Product Name	CLEARKLENS IPA VH1		
Product Code	<input type="checkbox"/> 101105062	<input checked="" type="checkbox"/> 101105063	<input type="checkbox"/> 101105064
Batch Number	FMP23235	58104	
Production Date	23/08/2023		
Expiration Date	EXP 23/08/2025		

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	0.875

Control of the Sterility of the product:

Test	Test Method	Specification	Conformity	Reference No:
Sterilization	Gamma Irradiation	25.0 - 45.0 (kGy)	YES	58104
Sterility Certificate	Sterility by Mebrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	YES	UK233333-25114
2.6.14 Bacterial Endotoxins	Method C - Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	UK233333-25115

	Date of released on behalf of Diversey's Manufacturing Location:	Testers:	
		Justyna Staron	07/09/2023
		Edyta Rodrigues	07/09/2023
		Quality Control Inspector	
		Olga Kirchner	02/10/2023

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

08/30/2023 9:12:20 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3403064
P.O.#	406151			Sales Order #	3377394
	25 - 45 kGy	Gamma Irradiation	Irradiation Date/Time:	00:00:00 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	527	BX	101101081	Diversey Clearklens DE 900ml	FMP23233	57904/STR002096
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	4	BX	101101081_SAMPLE	Diversey Clearklens DE 900ml	FMP23233	57904/STR002096
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	319	BX	101105063	Clearklens IPA 900 mls	FMP23235	58104/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	27.4 KGY	Pass	EMORRIS	08/26/2023 15:26:38 GMT
		Reason Code Test				EDWARD MORRIS	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.0 KGY	Pass	EMORRIS	08/26/2023 15:27:07 GMT
		Reason Code Test				EDWARD MORRIS	

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: 08/30/2023 09:08:34 GMT

R55480102

09/04/2023 13:29:46 GMT
Page 1 of 1

Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3406177
P.O.#	406179			Sales Order #	3381235
	25 - 45 kGy	Gamma Irradiation	Irradiation Date/Time:		00:00:00 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	500	BX	101105063	Clearklens IPA 900 mls	FMP23235	58104/STR002201
			Dose Map	RF: 13.5A3, AF Min: 0.717		
	500	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	CCICALA	09/04/2023 08:39:52 GMT
		Reason Code Test				CLAIRE CICALA	
450.00	Minimum Dose	25.0 kGy	45.0 kGy	27.3 KGY	Pass	CCICALA	09/04/2023 08:40:12 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: 09/04/2023 13:28:23 GMT

R55480102

09/06/2023 9:18:31 GMT
Page 1 of 1

Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3406779
P.O.#	406190			Sales Order #	3382109
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	00:00:00 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	610	BX	101105063	Clearklens IPA 900 mls	FMP23235	58104/STR00220
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	15	BX	101105063_SAMPLE	Clearklens IPA 900 mls	FMP23235	58104/STR00220
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
	625	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	38.9 KGY	Pass	CCICALA	09/04/2023 08:40:47 GMT
		Reason Code Test				CLAIRE CICALA	
450.00	Minimum Dose	25.0 kGy	45.0 kGy	27.5 KGY	Pass	CCICALA	09/04/2023 08:41:03 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: CLAIRES CICALA
Reason: Work Order Completions

Date: 09/04/2023 13:28:48 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: Fmp23235 58104

Lucideon Sample Number: UK233333-25114

Lucideon Report Number: UK233333-25114/MFEP **Issue Number:** 1

Date Logged: 08-Sep-2023 **Order Number:** 406254

Date Reported: 29-Sep-2023 **Date(s) of Test(s):** 14-Sep-2023 to 28-Sep-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

DocuSigned by:

Natalie Boot



Signer Name: Natalie Boot
Signing Reason: I have reviewed this document
Signing Time: 29 September 2023 | 16:03 BST

90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

Senior Business Support Administrator

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PHARMACEUTICAL ANALYSIS REPORT

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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: Fmp23235 58104

Lucideon Sample Number: UK233333-25115

Lucideon Report Number: UK233333-25115/ETEP **Issue Number:** 1

Date Logged: 08-Sep-2023 **Order Number:** 406254

Date Reported: 19-Sep-2023 **Date(s) of Test(s):** 18-Sep-2023 to 18-Sep-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

Testing performed at the Brooms Road, Stone facility in compliance with GMP, pending GMP certification.

End of Test Report

DocuSigned by:

Natalie Boot



Signer Name: Natalie Boot
Signing Reason: I have reviewed this document
Signing Time: 19 September 2023 | 11:08 BST

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Mrs Natalie Boot

Senior Business Support Administrator

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