

CERTIFICATE OF ANALYSIS

Date issue: 26 June 2023


Product Name	CLEARLENs IPA VH1		
Product Code	<input checked="" type="checkbox"/> 101105062	<input type="checkbox"/> 101105063	<input type="checkbox"/> 101105064
Batch Number	FMP23157	57363	
Production Date	06/06/2023		
Expiration Date	EXP 06/06/2025		

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	57363
Sterility Certificate	Sterility by Membrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	YES	UK232365-16342
2.6.14 Bacterial Endotoxins	Method C - Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	UK232365-16343

	Date of released on behalf of Diversey's Manufacturing Location:	Testers:	
		Natalia Traichel	26/06/2023
		Justyna Staron	26/06/2023
		Quality Control Inspector	
		Olga Kirchner	25/07/2023

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

06/19/2023 12:25:39 GMT
Page 1 of 1

Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3358947
P.O.#	405479			Sales Order #	3325652
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	06/18/2023 07:54:25 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	452	BX	101105062	Diversey Clearklens IPA 900ml	FMP23146	57362/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	3	BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP23146	57362/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	495	BX	101105062	Diversey Clearklens IPA 900ml	FMP23157	57363/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	CCICALA	06/19/2023 10:57:58 GMT
		Reason Code Test				CLAIRE CICALA	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.6 KGY	Pass	CCICALA	06/19/2023 11:56:14 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: CLAIRES CICALA
Reason: Work Order Completions

Date: 06/19/2023 12:21:31 GMT

R55480102

 06/19/2023 12:25:56 GMT
 Page 1 of 1

Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3361486
P.O.#	405505			Sales Order #	3328469
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	06/18/2023 11:51:00 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	802	BX	101105062	Diversey Clearklens IPA 900ml	FMP23157	57363/STR002199
			Dose Map	RF: 13.5A3, AF Min: 0.717		
102.000	23	BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP23157	57363/STR002199
			Dose Map	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	CCICALA	06/19/2023 10:57:27 GMT
		Reason Code Test				CLAIRE CICALA	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.1 KGY	Pass	JYATES	06/19/2023 04:18:45 GMT
		Reason Code Test				JOHN YATES	

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: 06/19/2023 12:20:24 GMT

PHARMACEUTICAL ANALYSIS REPORT

LUCIDEON

insight creating advantage

Flexible Medical Packaging

Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

This report supersedes the report
dated 24 July 2023 Ref:
UK232365-16342 Sterility Testing.

FAO: Mrs. Olga Kirchner

Report of Tests on: ClearKlens IPA

Sample Description: Sample Code: Fmp23157 57363

Lucideon Sample Number: UK232365-16342

Lucideon Report Number: UK232365-16342/MFEP **Issue Number:** 2

Date Logged: 27-Jun-2023 **Order Number:** 405639

Date Reported: 19-Oct-2023 **Date(s) of Test(s):** 06-Jul-2023 to 20-Jul-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: 19 October 2023 | 10:46 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: Fmp23157 57363

Lucideon Sample Number: UK232365-16343

Lucideon Report Number: UK232365-16343/ETEP **Issue Number:** 1

Date Logged: 27-Jun-2023 **Order Number:** 405639

Date Reported: 13-Jul-2023 **Date(s) of Test(s):** 11-Jul-2023 to 11-Jul-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

DocuSigned by:

Natalie Boot



Signer Name: Natalie Boot
Signing Reason: I have reviewed this document
Signing Time: 13 July 2023 | 17:01 BST

90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

Senior Business Support Administrator

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