

CERTIFICATE OF ANALYSIS

Date issue: 07 July 2023

Product Name	CLEARLENs IPA VH1		
Product Code	<input checked="" type="checkbox"/> 101105062	<input type="checkbox"/> 101105063	<input type="checkbox"/> 101105064
Batch Number	FMP 23173	57442	
Production Date	22/06/2023		
Expiration Date	EXP 22/06/2025		

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	57442
Sterility Certificate	Sterility by Membrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII	No Growth	YES	UK232601-19436
2.6.14 Bacterial Endotoxins	Method C - Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	UK232601-19437

	Date of released on behalf of Diversey's Manufacturing Location:	Testers:	
		Sabcho Svetoslavov	07/07/2023
		Angelika Pietraszko	07/07/2023
		Quality Control Inspector	
		Olga Kirchner	02/08/2023

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

 07/04/2023 9:22:02 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3369299
P.O.#	405633			Sales Order #	3337687
	25 - 45 kGy	Gamma Irradiation	Irradiation Date/Time:	07/01/2023 02:55:35 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	131	BX	101105062	Diversey Clearklens IPA 900ml	FMP23172	58237/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	3	BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP23172	58237/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	841	BX	101105062	Diversey Clearklens IPA 900ml	FMP23173	57442/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
	975	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	39.2 KGY	Pass	BCZAPLA	07/02/2023 04:41:17 GMT
		Reason Code Test				BARTOSZ CZAPLA	
450.00	Minimum Dose	25.0 kGy	45.0 kGy	27.7 KGY	Pass	BCZAPLA	07/02/2023 04:41:56 GMT
		Reason Code Test				BARTOSZ CZAPLA	

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: STEVEN WHELAN
 Reason: Work Order Completions

Date: 07/04/2023 09:21:43 GMT

R55480102

 07/04/2023 10:51:03 GMT
 Page 1 of 1

Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3370369
P.O.#	405653			Sales Order #	3338920
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	07/01/2023 07:21:48 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	596	BX	101105062	Diversey Clearklens IPA 900ml	FMP23173	57442/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	3	BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP23173	57442/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	376	BX	101105062	Diversey Clearklens IPA 900ml	FMP23178	57443/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
	975	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	BCZAPLA	07/02/2023 04:44:04 GMT
		Reason Code Test				BARTOSZ CZAPLA	
450.00	Minimum Dose	25.0 kGy	45.0 kGy	27.5 KGY	Pass	BCZAPLA	07/02/2023 04:44:20 GMT
		Reason Code Test				BARTOSZ CZAPLA	

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: STEVEN WHELAN
 Reason: Work Order Completions

Date: 07/04/2023 10:50:41 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: Fmp23173 57442

Lucideon Sample Number: UK232601-19436

Lucideon Report Number: UK232601-19436/MFEP **Issue Number:** 1

Date Logged: 10-Jul-2023 **Order Number:** 405740

Date Reported: 02-Aug-2023 **Date(s) of Test(s):** 18-Jul-2023 to 01-Aug-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: 02 August 2023 | 09:32 BST

90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

Senior Business Support Administrator

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PHARMACEUTICAL ANALYSIS REPORT

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: Fmp23173 57442

Lucideon Sample Number: UK232601-19437

Lucideon Report Number: UK232601-19437/ETEP **Issue Number:** 1

Date Logged: 10-Jul-2023 **Order Number:** 405740

Date Reported: 19-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:

Tracy Wheeler

Signer Name: Tracy Wheeler
Signing Reason: I have reviewed this document
Signing Time: 19 July 2023 | 11:20 BST

D85AB0246E184F31821E2EC1AFA6CA90

Tracy Wheeler

Business Support Administrator

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