

CERTIFICATE OF ANALYSIS

Date issue: 19 April 2023


Product Name	CLEARLENs IPA VH1		
Product Code	<input checked="" type="checkbox"/> 101105062	<input type="checkbox"/> 101105063	<input type="checkbox"/> 101105064
Batch Number	FMP23095	57627	
Production Date	05/04/2023		
Expiration Date	EXP 05/04/2025		

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	57627
Sterility Certificate	Sterility by Membrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	YES	UK231452-9940
2.6.14 Bacterial Endotoxins	Method C - Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	UK231452-9941

	Date of released on behalf of Diversey's Manufacturing Location:	Testers:	
		Sabcho Svetoslavov	19/04/2023
		Justyna Staron	19/04/2023
		Quality Control Inspector	
		Olga Kirchner	16/05/2023

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

04/17/2023 8:59:34 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3322445
P.O.#	405012			Sales Order #	3282914
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	04/15/2023 01:44:11 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	302	BX	101105062	Diversey Clearklens IPA 900ml	FMP23094	57626/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	3	BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP23094	57626/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	177	BX	101105062	Diversey Clearklens IPA 900ml	FMP23095	57627/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
104.000	18	BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP23095	57627/STR002199
	Dose Map		302_0112	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	Minimum Dose	25.0 kGy	45.0 kGy	27.1 KGY	Pass	JATKINSON	04/15/2023 17:21:37 GMT
		Reason Code Test				JOE ATKINSON	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.0 KGY	Pass	JATKINSON	04/15/2023 17:22:02 GMT
		Reason Code Test				JOE ATKINSON	

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: 04/17/2023 08:55:50 GMT

PHARMACEUTICAL ANALYSIS REPORT



Flexible Medical Packaging

Jnit 8
Lighttown
White Cross Industrial Estate
Lancaster
LA1 4XS

FAO: Mr. Luka Davies

Report of Tests on: ClearKlens IPA

Sample Description: Sample Code: Fmp23095 57627

Lucideon Sample Number: UK231452-9941

Lucideon Report Number: UK231452-9941/ETEP **Issue Number:** 1

Date Logged: 21-Apr-2023 **Order Number:** 405082

Date Reported: 03-May-2023 **Date(s) of Test(s):** 01-May-2023 to 01-May-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: 03 May 2023 | 11:40 BST
90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

Senior Business Support Administrator

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PHARMACEUTICAL ANALYSIS REPORT

LUCIDEON

insight creating advantage

Flexible Medical Packaging

Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

FAO: Mr. Luka Davies

Report of Tests on: ClearKlens IPA

Sample Description: Sample Code: Fmp23095 57627

Lucideon Sample Number: UK231452-9940

Lucideon Report Number: UK231452-9940/MFEP **Issue Number:** 1

Date Logged: 21-Apr-2023 **Order Number:** 405082

Date Reported: 16-May-2023 **Date(s) of Test(s):** 28-Apr-2023 to 12-May-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:

Tracy Wheeler

Signer Name: Tracy Wheeler
Signing Reason: I have reviewed this document
Signing Time: 16 May 2023 | 11:01 BST
D85AB0246E184F31821E2EC1AFA6CA90

Tracy Wheeler

Business Support Administrator

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