

CERTIFICATE OF ANALYSIS

Date issue: 04 August 2023

Product Name	CLEARLENs IPA VH1		
Product Code	<input checked="" type="checkbox"/> 101105062	<input type="checkbox"/> 101105063	<input type="checkbox"/> 101105064
Batch Number	FMP23200	57761	
Production Date	19/07/2023		
Expiration Date	EXP 19/07/2025		

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	57761
Sterility Certificate	Sterility by Membrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	YES	UK2333007-22815
2.6.14 Bacterial Endotoxins	Method C - Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	UK2333007-22816

	Date of released on behalf of Diversey's Manufacturing Location:	Testers:	
		Sabcho Svetoslavov	04/08/2023
		Angelika Pietraszko	04/08/2023
		Quality Control Inspector	
		Olga Kirchner	06/09/2023

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

07/26/2023 7:37:50 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3383140
P.O.#	405859			Sales Order #	3353784
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	07/22/2023 06:48:00 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	130	BX	101105062	Diversey Clearklens IPA 900ml	FMP23200	57761/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	717	BX	101105063	Clearklens IPA 900 mls	FMP23198	57756/STR002201
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	3	BX	101105063_SAMPLE	Clearklens IPA 900 mls	FMP23198	57756/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	27.3 KGY	Pass	SWHELAN	07/24/2023 09:50:28 GMT
		Reason Code Test				STEVEN WHELAN	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.1 KGY	Pass	SWHELAN	07/24/2023 09:50:48 GMT
		Reason Code Test				STEVEN WHELAN	

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: 07/26/2023 07:37:27 GMT

R55480102

07/31/2023 10:02:39 GMT
Page 1 of 1

Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3384359
P.O.#	405878			Sales Order #	3355293
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	07/29/2023 11:27:27 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	950	BX	101105062	Diversey Clearklens IPA 900ml	FMP23200	57761/STR002199
			Dose Map	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	27.2 KGY	Pass	PSAXTON	07/30/2023 03:24:12 GMT
		Reason Code Test				PAUL SAXTON	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	38.9 KGY	Pass	PSAXTON	07/30/2023 03:24:30 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: STEVEN WHELAN
Reason: Work Order Completions

Date: 07/31/2023 10:02:07 GMT

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07/31/2023 10:02:39 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3387455
P.O.#	405910			Sales Order #	3358608
	25 - 45 kGy	Gamma Irradiation	Irradiation Date/Time:	07/29/2023 15:36:36 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	542	BX	100862174	Diversey Clearklens DE 900 mL	FMP23205	57759/STR001910
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	355	BX	101105062	Diversey Clearklens IPA 900ml	FMP23200	57761/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	3	BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP23200	57761/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
	900	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	38.6 KGY	Pass	BCZAPLA	07/30/2023 03:25:44 GMT
		Reason Code Test				BARTOSZ CZAPLA	
450.00	Minimum Dose	25.0 kGy	45.0 kGy	26.8 KGY	Pass	BCZAPLA	07/30/2023 03:26:03 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: 07/31/2023 10:01:41 GMT

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: Fmp23200 57761

Lucideon Sample Number: UK233007-22816

Lucideon Report Number: UK233007-22816/ETEP Issue Number: 1

Date Logged: 07-Aug-2023 Order Number: 405987

Date Reported: 18-Aug-2023 Date(s) of Test(s): 17-Aug-2023 to 17-Aug-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: 18 August 2023 | 14:25 BST

80369E9048134123B65D5E8FBD375BF3

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: Fmp23200 57761

Lucideon Sample Number: UK233007-22815

Lucideon Report Number: UK233007-22815/MFEP **Issue Number:** 1

Date Logged: 07-Aug-2023 **Order Number:** 405987

Date Reported: 05-Sep-2023 **Date(s) of Test(s):** 22-Aug-2023 to 05-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: 05 September 2023 | 16:00 BST
90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

Senior Business Support Administrator

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