

CERTIFICATE OF ANALYSIS

Date issue: 27 November 2023

Product Name	CLEARLENs IPA VH1		
Product Code	<input checked="" type="checkbox"/> 101105062	<input type="checkbox"/> 101105063	<input type="checkbox"/> 101105064
Batch Number	FMP23300	58737	
Production Date	27/10/2023		
Expiration Date	EXP 27/10/2025		

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	58737
Sterility Certificate	Sterility by Membrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	YES	UK234357-32904
2.6.14 Bacterial Endotoxins	Method C - Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	UK234357-32905

	Date of released on behalf of Diversey's Manufacturing Location:	Testers:
		Natalia Traichel 27/11/2023
		Angelika Pietraszko 27/11/2023
		Quality Control Inspector Olga Kirchner 18/12/2023

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

 11/06/2023 11:17:43 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3443411
P.O.#	406683			Sales Order #	3424552
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	11/02/2023 23:49:29 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	536	BX	101105062	Diversey Clearklens IPA 900ml	FMP23294	58575/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	3	BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP23294	58575/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	186	BX	101105062	Diversey Clearklens IPA 900ml	FMP23300	58737/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
	725	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	28.2 KGY	Pass	JATKINSON	11/04/2023 02:57:11 GMT
		Reason Code Test				JOE ATKINSON	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.9 KGY	Pass	JATKINSON	11/04/2023 02:57:37 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: CLAIRE CICALA
 Reason: Work Order Completions

Date: 11/06/2023 11:14:49 GMT

Certificate of Processing

STERIGENICS Seymour Link Road Woodthorpe Mastin Moor
 TEL (0)1246 561230 FAX www.sterigenics.com

R55480102

11/20/2023 13:49:02 GMT
 Page 1 of 1

Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3446048
P.O.#	406727			Sales Order #	3427774
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	11/17/2023 04:36:55 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	1075	BX	101105062	Diversey Clearklens IPA 900ml	FMP23300	58737/STR002199
			Dose Map	RF: 13.5A3, AF Min: 0.717		
	1075	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	JATKINSON	11/17/2023 17:54:20 GMT
		Reason Code Test				JOE ATKINSON	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.4 KGY	Pass	RGATES2	11/20/2023 11:47:55 GMT
		Reason Code Test				RHIANNON GATES	

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: RHIANNON GATES
 Reason: Work Order Completions

Date: 11/20/2023 13:45:03 GMT

R55480102

11/20/2023 13:49:24 GMT
Page 1 of 1

Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3446057
P.O.#	406728			Sales Order #	3427783
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	11/17/2023 09:18:56 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	885	BX	101105062	Diversey Clearklens IPA 900ml	FMP23300	58737/STR002199
			302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	15	BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP23300	58737/STR002199
			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	39.7 KGY	Pass	RGATES2	11/20/2023 11:50:47 GMT
		Reason Code Test				RHIANNON GATES	
450.00	Minimum Dose	25.0 kGy	45.0 kGy	27.5 KGY	Pass	LDAWSON	11/18/2023 01:01:51 GMT
		Reason Code Test				LINDSAY DAWSON	

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: RHIANNON GATES
Reason: Work Order Completions

Date: 11/20/2023 13:45:54 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: Fmp23300 58737

Lucideon Sample Number: UK234357-32904

Lucideon Report Number: UK234357-32904/MFEP **Issue Number:** 1

Date Logged: 28-Nov-2023 **Order Number:** 406940

Date Reported: 15-Dec-2023 **Date(s) of Test(s):** 30-Nov-2023 to 14-Dec-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: 15 December 2023 | 13:54 GMT

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:Fmp23300 58737

Lucideon Sample Number: UK234357-32905

Lucideon Report Number: UK234357-32905/ETEP **Issue Number:** 1

Date Logged: 28-Nov-2023 **Order Number:** 406940

Date Reported: 14-Dec-2023 **Date(s) of Test(s):** 07-Dec-2023 to 07-Dec-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: 14 December 2023 | 09:49 GMT

90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

Senior Business Support Administrator

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