

CERTIFICATE OF ANALYSIS

Date issue: 07 August 2024


Product Name	CLEARLENs IPA VH1 S 6x0.9L		
Product Code	<input checked="" type="checkbox"/> 101105062	<input type="checkbox"/> 101105063	<input type="checkbox"/> 101105064
Batch Number	FMP24197	60300	
Production Date	15/07/2024		
Expiration Date	EXP 15/07/2026		

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	60300
Sterility Certificate	Sterility by Membrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	YES	UK242675 - 18171
2.6.14 Bacterial Endotoxins	Method C - Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	UK242675 - 18172

	Date of released on behalf of Diversey's Manufacturing Location:	Testers:	
		Edyta Rodrigues	07/08/2024
		Justyna Staron	07/08/2024
		Quality Control Inspector	
		Caroline Pascoe	23/08/2024

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

08/02/2024 8:10:30 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3593211
P.O.#	408632			Sales Order #	3600946
25 - 45 kGy		Gamma Irradiation		Irradiation Date/Time:	07/31/2024 20:31:57 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	FMP24197	FMP60300 - STR002199
			Dose Map	RF: 13.5A3, AF Min: 0.717		
	1075	BX	Total			

Quality Test Summary							-----Signed By-----
Op#	Quality Test Description	Minimum Spec	Maximum Spec	Result	Pass/Fail	User	Date /Time
450.00	Minimum Dose	25.0 kGy	45.0 kGy	27.9 KGY	Pass	PSAXTON	08/01/2024 17:46:47 GMT
		Reason Code Test				PAUL SAXTON	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.7 KGY	Pass	CCICALA	08/02/2024 07:54:06 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: 08/02/2024 08:09:43 GMT

R55480102

 08/02/2024 8:47:46 GMT
 Page 1 of 1

Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3593782
P.O.#	408637			Sales Order #	3601692
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	08/01/2024 03:16:03 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	1071	BX	101105062	Diversey Clearklens IPA 900ml	FMP24197	60300/STR002199
			302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	4	BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP24197	60300/STR002199
			302_0112	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	27.1 KGY	Pass	PSAXTON	08/01/2024 17:44:20 GMT
		Reason Code Test				PAUL SAXTON	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.0 KGY	Pass	PSAXTON	08/01/2024 17:44:38 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: CLAIRE CICALA
 Reason: Work Order Completions

Date: 08/02/2024 08:47:32 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: Fmp24197 60300

Lucideon Sample Number: UK242675-18171

Lucideon Report Number: UK242675-18171/MFEP **Issue Number:** 1

Date Logged: 08-Aug-2024 **Order Number:** 408737

Date Reported: 22-Aug-2024 **Date(s) of Test(s):** 08-Aug-2024 to 22-Aug-2024

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

Signed by:

Natalie Boot



Signer Name: Natalie Boot
Signing Reason: I have reviewed this document
Signing Time: 22 August 2024 | 16:50 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: ClerKlens IPA

Sample Description: Sample Code: Fmp24197 60300

Lucideon Sample Number: UK242675-18172

Lucideon Report Number: UK242675-18172/ETEP **Issue Number:** 1

Date Logged: 08-Aug-2024 **Order Number:** 408737

Date Reported: 19-Aug-2024 **Date(s) of Test(s):** 13-Aug-2024 to 13-Aug-2024

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

Signed by:

Natalie Boot



Signer Name: Natalie Boot
Signing Reason: I have reviewed this document
Signing Time: 19 August 2024 | 12:47 BST
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Mrs Natalie Boot

Senior Business Support Administrator

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