

CERTIFICATE OF ANALYSIS

Date issue: 31 October 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	FMP24284	60818	
Production Date	10/10/2024		
Expiration Date	EXP 10/10/2026		

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	60818
Sterility Certificate	Sterility by Membrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	YES	UK243688-25109
2.6.14 Bacterial Endotoxins	Method C - Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	UK243688-25110

	Date of released on behalf of Diversey's Manufacturing Location:	Testers:	
		Justyna Staron	31/10/2024
		Angelika Pietraszko	31/10/2024
		Quality Control Inspector	
		Olga Kirchner	20/11/2024

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

10/21/2024 8:50:50 GMT
Page 1 of 1

Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3641884
P.O.#	409225			Sales Order #	3661065
	25 - 45 kGy	Gamma Irradiation	Irradiation Date/Time:	10/19/2024 03:52:59 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	FMP24284	60818/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	27.2 KGY	Pass	JYATES	10/19/2024 16:31:41 GMT
		Reason Code Test				JOHN YATES	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.1 KGY	Pass	JYATES	10/19/2024 16:31:57 GMT
		Reason Code Test				JOHN YATES	

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-MAESTRE
Reason: Work Order Completions

Date: 10/21/2024 08:47:48 GMT

R55480102

10/28/2024 9:16:22 GMT
Page 1 of 1

Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3645287
P.O.#	409250			Sales Order #	3665104
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	10/26/2024 02:51:35 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	1047	BX	101105062	Diversey Clearklens IPA 900ml	FMP24284	60818/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	3	BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP24284	60818/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
	1050	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	IWEATHERAL	10/26/2024 17:19:27 GMT
		Reason Code Test				IAN WEATHERALL	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.2 KGY	Pass	IWEATHERAL	10/26/2024 17:19:51 GMT
		Reason Code Test				IAN WEATHERALL	

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-MAESTRE
Reason: Work Order Completions

Date: 10/28/2024 09:15:16 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: FMP24284 60818

Lucideon Sample Number: UK243688-25109

Lucideon Report Number: UK243688-25109/MFEP **Issue Number:** 1

Date Logged: 01-Nov-2024 **Order Number:** 409335

Date Reported: 19-Nov-2024 **Date(s) of Test(s):** 04-Nov-2024 to 18-Nov-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: 19 November 2024 | 14:57 GMT

90369E9048134123B65D5E8FBD375BF3

Mrs Natalie Boot

Senior Business Support Administrator

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Reg. England 1960455

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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: FMP24284 60818

Lucideon Sample Number: UK243688-25110

Lucideon Report Number: UK243688-25110/ETEP **Issue Number:** 1

Date Logged: 01-Nov-2024 **Order Number:** 409335

Date Reported: 12-Nov-2024 **Date(s) of Test(s):** 08-Nov-2024 to 08-Nov-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: 12 November 2024 | 12:14 GMT

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Mrs Natalie Boot

Senior Business Support Administrator

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Certified Delivered

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Signing Complete

Security Checked

12-Nov-24 | 12:14

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Security Checked

12-Nov-24 | 12:14

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