

CERTIFICATE OF ANALYSIS

Date issue: 05/08/2022


Product Name	DI ClearKlens IPA VH1 S 6x0.9L
Product Code	<input checked="" type="checkbox"/> 101105062/ <input type="checkbox"/> 101105063/ <input type="checkbox"/> 101105064
Batch Number	FMP22195; 55051
Production date	14/07/2022
Expiration Date	EXP 14/07/2024

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	Unit	Results
Appearance	Visual	Colourless Clear Liquid	N/A	Colourless Clear Liquid
Specific Gravity (20°C)	DM 004	0.872 - 0.883	g/cm ³	0.875

Control of the Sterility of the product:

Test	Test Method	Specification	Conformity	Reference number
Sterilization	Gamma Irradiation	25.0 – 45.0 (kGy)	YES	55051
Sterility certificate	Sterility by Membrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	YES	UK223178-20393
2.6.14 Bacterial Endotoxins	Method C – Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	UK223178-20394

	Date of released On behalf of Diversey's Manufacturing location: 12/09/2022	by : Olga Kirchner Position: QA Admin
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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

 07/25/2022 8:46:22 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3160657
P.O.#	403050			Sales Order #	3093157
	25 - 45 kGy	Gamma Irradiation		Irradiation Date/Time:	07/23/2022 06:51:41 GMT

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	450	BX	101105062	Diversey Clearklens IPA 900ml	FMP22195	55051/STR002199
			Dose Map	RF: 13.5A3, AF Min: 0.717		
	450	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	27.4 KGY	Pass	JBARRATT	07/23/2022 16:49:33 GMT
		Reason Code Test				JAMIE BARRATT	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	38.7 KGY	Pass	JBARRATT	07/23/2022 16:49:51 GMT
		Reason Code Test				JAMIE BARRATT	

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: 07/25/2022 08:41:05 GMT

R55480102

09/12/2022 9:43:30 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3165347
P.O.#	403101			Sales Order #	3098472
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	07/30/2022 13:23:10 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	972	BX	101105062	Diversey Clearklens IPA 900ml	FMP22195	55051
			302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	3	BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP22195	55051
			302_0112	RF: 13.5A3, AF Min: 0.717		
	975	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	40.1 KGY	Pass	BCZAPLA BARTOSZ CZAPLA	07/31/2022 05:04:21 GMT
450.00	Minimum Dose	25.0 kGy	45.0 kGy	27.5 KGY	Pass	BCZAPLA BARTOSZ CZAPLA	07/31/2022 05:04:40 GMT
		Reason Code Test					

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: **09/12/2022 09:43:09 GMT**

PHARMACEUTICAL ANALYSIS REPORT

LUCIDEON

insight creating advantage

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: Fmp22195 55051

Lucideon Sample Number: UK223178-20393

Lucideon Report Number: UK223178-20393/MFEP **Issue Number:** 1

Date Logged: 08-Aug-2022 **Order Number:** 403167

Date Reported: 08-Sep-2022 **Date(s) of Test(s):** 23-Aug-2022 to 06-Sep-2022

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

NBBook 08-Sep-22

Mrs Natalie Boot

Senior Business Support Administrator

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Unit 8
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LA1 4XS

FAO: Mrs.Olga Kirchner

Report of Tests on: ClearKlens IPA

Sample Description: Sample Code: Fmp22195 55051

Lucideon Sample Number: UK223178-20394

Lucideon Report Number: UK223178-20394/ETEP **Issue Number:** 1

Date Logged: 08-Aug-2022 **Order Number:** 403167

Date Reported: 22-Aug-2022 **Date(s) of Test(s):** 21-Aug-2022 to 21-Aug-2022

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

Natalie Boot 22-Aug-22

Mrs Natalie Boot

Senior Business Support Administrator

Page 1 of 1

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