

CERTIFICATE OF ANALYSIS

Date issue: 14/09/2022


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	FMP22041; 53926
Production date	10/02/2022
Expiration Date	EXP 10/02/2024

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	53926
Sterility certificate	Sterility by Membrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	YES	UK221148-7245
2.6.14 Bacterial Endotoxins	Method C – Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	UK221148-7246

	Date of released On behalf of Diversey's Manufacturing location: 19/04/2022	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

 03/07/2022 10:24:26 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3070703
P.O.#	402063			Sales Order #	2987713
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	03/05/2022 11:58:15 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	596	BX	101105062	Diversey Clearklens IPA 900ml	FMP22041	53926/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	3	BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP22041	53926/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	351	BX	101105062	Diversey Clearklens IPA 900ml	FMP22053	53927/STR002199
	Dose Map		302_0112	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	28.0 KGY	Pass	JYATES	03/06/2022 06:23:39 GMT
		Reason Code Test				JOHN YATES	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	40.2 KGY	Pass	JYATES	03/06/2022 06:24:02 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: EMMA SILLS
 Reason: Work Order Completions

Date: 03/07/2022 10:24:15 GMT

R55480102

02/28/2022 11:12:00 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3064094
P.O.#	401997			Sales Order #	2979992
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	02/26/2022 00:38:34 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	828	BX	101105062	Diversey Clearklens IPA 900ml	FMP22041	53926/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	119	BX	101105063	Clearklens IPA 900 mls	FMP22032	53606/STR002201
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	3	BX	101105063_SAMPLE	Clearklens IPA 900 mls	FMP22032	53606/STR002201
	Dose Map		302_0112	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	27.4 KGY	Pass	DMATHIAS	02/27/2022 05:01:36 GMT
		Reason Code Test				DAVID MATHIAS	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.9 KGY	Pass	DMATHIAS	02/27/2022 05:02:09 GMT
		Reason Code Test				DAVID MATHIAS	

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: 02/28/2022 10:48:29 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: FMP22041 53926

Lucideon Sample Number: UK221148-7245

Lucideon Report Number: UK221148-7245/MFEP

Issue Number: 1

Date Logged: 15-Mar-2022

Order Number: 402165

Date Reported: 05-Apr-2022

Date(s) of Test(s): 19-Mar-2022 to 02-Apr-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

and 05 APR 22

Charlotte Arnold

Client Technical Support

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PHARMACEUTICAL ANALYSIS REPORT

LUCIDEON

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Flexible Medical Packaging

Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

Supplement to Test Report dated 14
April 2022 Ref: UK221148-7246
Endotoxin Testing.

FAO: Mrs.Olga Kirchner

Report of Tests on: ClearKlens IPA

Sample Description: Sample Code: FMP22041 53926

Lucideon Sample Number: UK221148-7246

Lucideon Report Number: UK221148-7246/ETEP

Issue Number: 2

Date Logged: 15-Mar-2022

Order Number: 402165

Date Reported: 04-Nov-2022

Date(s) of Test(s): 05-Apr-2022 to 09-Apr-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 (<0.2000EU/ml)*

Tests carried out in accordance with cGMP

*Re-test results as part of LIR4781 - see LIR result report UK221148-7246/PM Issue 1 for all test results.

End of Test Report

Natalie Boot 22

Mrs Natalie Boot

Senior Business Support Administrator

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