

CERTIFICATE OF ANALYSIS

Date issue: 17 March 2022


Product Name	DI ClearKlens IPA VH1 S 6x0.9L
Product Code	☒101105062/☐101105063/☐101105064
Batch Number	FMP22053 53927
Production date	22/02/2022
Expiration Date	EXP 22/02/2024

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	0.873

Control of the Sterility of the product:

Test	Test Method	Specification	Conformity	Reference number
Sterilization	Gamma Irradiation	25.0 – 45.0 (kGy)	YES	53927
Sterility certificate	Sterility by Membrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	YES	UK221201-7564
2.6.14 Bacterial Endotoxins	Method C – Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	YES	UK221201-7565

	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

 03/14/2022 16:08:25 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3073543
P.O.#	402090			Sales Order #	2991008
	25 - 45 kGy	Gamma Irradiation	Irradiation Date/Time:	03/12/2022 09:35:12 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	226	BX	100862174	Diversey Clearklens DE 900 mL	FMP22060	54178/STR001910
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	696	BX	101105062	Diversey Clearklens IPA 900ml	FMP22053	53927/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	3	BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP22053	53927/STR002199
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
	925	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	27.7 KGY	Pass	PSAXTON	03/12/2022 23:02:50 GMT
		Reason Code Test				PAUL SAXTON	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.5 KGY	Pass	ESILLS	03/14/2022 11:50:59 GMT
		Reason Code Test				EMMA SILLS	

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: 03/14/2022 16:08:04 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: FMP22053 53927

Lucideon Sample Number: UK221201-7564

Lucideon Report Number: UK221201-7564/MFEP **Issue Number:** 1

Date Logged: 18-Mar-2022 **Order Number:** PO 402212

Date Reported: 08-Apr-2022 **Date(s) of Test(s):** 22-Mar-2022 to 05-Apr-2022

Sterility Testing

Membrane Filtration EP

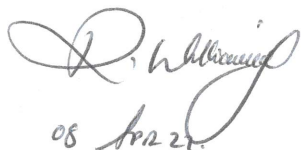
Test Results:

The test results meet the EP/USP criteria: Yes

Result: Pass

Tests carried out in accordance with cGMP

End of Test Report



08 Apr 22

Robin Williams

Microbiology Laboratory Supervisor

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Lucideon Limited
Queens Road, Penkhull
Stoke-on-Trent
Staffordshire ST4 7LQ

T +44 (0)1782 764428
enquiries@lucideon.com
www.lucideon.com

PHARMACEUTICAL ANALYSIS REPORT

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LA1 4XS

Supplement to Test Report dated 14
April 2022 Ref: UK221201-7565
Endotoxin Testing.

FAO: Mrs.Olga Kirchner

Report of Tests on: ClearKlens IPA

Sample Description: Sample Code: FMP22053 53927

Lucideon Sample Number: UK221201-7565

Lucideon Report Number: UK221201-7565/ETEP **Issue Number:** 2

Date Logged: 18-Mar-2022 **Order Number:** PO 402212

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 UK221201-7565/PM Issue 1 for all test results.

End of Test Report

Natalie Boot

Mrs Natalie Boot

Senior Business Support Administrator

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Lucideon Limited
Queens Road, Penkhull
Stoke-on-Trent
Staffordshire ST4 7LQ

T +44 (0)1782 764428
enquiries@lucideon.com
www.lucideon.com