

CERTIFICATE OF ANALYSIS

Date issue: 09/03/2022


Product Name	DI ClearKlens IPA VH1 S 6x0.9L
Product Code	<input type="checkbox"/> 101105062/ <input checked="" type="checkbox"/> 101105063/ <input type="checkbox"/> 101105064
Batch Number	FMP22032: 53606
Production date	01/02/2022
Expiration Date	EXP 01/02/2024

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	53606
Sterility certificate	Sterility by Membrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	Yes	UK221005-6608
2.6.14 Bacterial Endotoxins	Method C – Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	Yes	UK221005-6609

	Date of released On behalf of Diversey's Manufacturing location: 30/03/2022	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

02/14/2022 11:18:08 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3056731
P.O.#	401901			Sales Order #	2971852
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	02/11/2022 06:00:29 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	273	BX	101105063	Clearklens IPA 900 mls	FMP22021	53605/STR002201
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
102.000	3	BX	101105063_SAMPLE	Clearklens IPA 900 mls	FMP22021	53605/STR002201
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
103.000	434	BX	101105063	Clearklens IPA 900 mls	FMP22032	53606/STR002201
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
104.000	140	BX	101105063	Clearklens IPA 900 mls	54336	TO21/211
	Dose Map		302_0112	RF: 13.5A3, AF Min: 0.717		
	850	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	27.6 KGY	Pass	SWARD	02/11/2022 18:06:09 GMT
		Reason Code Test				SIMON WARD	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.7 KGY	Pass	SWARD	02/11/2022 18:06:31 GMT
		Reason Code Test				SIMON WARD	

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: 02/14/2022 11:17:58 GMT

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02/21/2022 10:30:51 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	3061187
P.O.#	401966			Sales Order #	2976801
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	02/18/2022 08:18:43 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	875	BX	101105063	Clearklens IPA 900 mls	FMP22032	53606/STR002201
			Dose Map	RF: 13.5A3, AF Min: 0.717		
	875	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	26.4 KGY	Pass	PSAXTON	02/18/2022 18:11:53 GMT
		Reason Code Test				PAUL SAXTON	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.6 KGY	Pass	PSAXTON	02/18/2022 18:12:18 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: EMMA SILLS
Reason: Work Order Completions

Date: 02/21/2022 10:30:37 GMT

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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: Clear Klens IPA

Sample Description: Sample Code: FMP22032 53606

Lucideon Sample Number: UK221005-6609

Lucideon Report Number: UK221005-6609/ETEP **Issue Number:** 1

Date Logged: 08-Mar-2022 **Order Number:** PO 402114

Date Reported: 18-Mar-2022 **Date(s) of Test(s):** 10-Mar-2022 to 10-Mar-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

NBBOOK 18-MAR-22

Mrs Natalie Boot

Senior Business Support Administrator

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PHARMACEUTICAL ANALYSIS REPORT

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Flexible Medical Packaging

Unit 8
Hightown
White Cross Industrial Estate
Lancaster
LA1 4XS

FAO: Mrs.Olga Kirchner

Report of Tests on: Clear Klens IPA

Sample Description: Sample Code: FMP22032 53606

Lucideon Sample Number: UK221005-6608

Lucideon Report Number: UK221005-6608/MFEP

Issue Number: 1

Date Logged: 08-Mar-2022

Order Number: PO 402114

Date Reported: 28-Mar-2022

Date(s) of Test(s): 11-Mar-2022 to 25-Mar-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

Clnt 28 MAR 22

Charlotte Arnold

Client Technical Support

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