

CERTIFICATE OF ANALYSIS

Date Issue: 09 July 2021


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	FMP21169 52071
Production date	18/06/2021
Expiration Date	EXP 18/06/2023

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	52071
Sterility certificate	Sterility by Membrane Filtration EP 9.0 2.6.1, USP 42<71> & JP XVII 4.06	No Growth	Yes	UK212989-20475
2.6.14 Bacterial Endotoxins	Method C – Turbidimetric Kinetic Method (EP/USP Criteria)	<0.2 EU/mL	Yes	UK212989-20476

	Date of released On behalf of Diversey's Manufacturing location: 09/07/2021	by : <i>CBear</i> Position: <i>QA ADMIN</i>
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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

 08/10/2021 8:56:50 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	2914185
P.O.#	400140			Sales Order #	2804362
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	07/03/2021 04:13:30 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
101.000	302	BX	101101081	Diversey Clearklens DE 900ml	FMP21165	WO51966/STR002096
	Dose Map		302_0112	REF: 13.5A3 AF Min = 0.717		
102.000	21	BX	101101081_SAMPLE	Diversey Clearklens DE 900ml	FMP21165	WO51966/STR002096
	Dose Map		302_0112	REF: 13.5A3 AF Min = 0.717		
106.000	602	BX	101105062	Diversey Clearklens IPA 900ml	FMP21169	WO52071/STR2199
	Dose Map		302_0112	REF: 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	27.6 KGY	Pass	DMARRIOTT	07/03/2021 16:57:15 GMT
		Reason Code Test				DAVID MARRIOTT	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	40.0 KGY	Pass	DMARRIOTT	07/03/2021 16:57:34 GMT
		Reason Code Test				DAVID MARRIOTT	

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: 08/10/2021 08:56:39 GMT

R55480102

 08/10/2021 9:02:07 GMT
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Customer Name:	FLEXIBLE MED. GBP UK LANCASTER	Processing Facility:	Markham Vale	Work Order #	2916004
P.O.#	400148			Sales Order #	2806512
25 - 45 kGy		Gamma Irradiation	Irradiation Date/Time:	07/03/2021 08:53:08 GMT	

SO Line #	Qty	UOM	Customer Item Number	Customer Item Description	Customer Lot Number	Customer Load Number
106.000	824	BX	101105062	Diversey Clearklens IPA 900ml	FMP21169	WO52071/STR002199
	Dose Map		302_0112	REF: 13.5A3 AF Min = 0.717		
108.000	3	BX	101105062_SAMPLE	Diversey Clearklens IPA 900ml	FMP21169	WO52071/STR002199
	Dose Map		302_0112	REF: 13.5A3 AF Min = 0.717		
109.000	123	BX	7513400	Diversey Clearklens IPA 900 mL	FMP21175	WO52072/STR002199
	Dose Map		302_0112	REF: 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	27.0 KGY	Pass	DMARRIOTT	07/03/2021 16:56:03 GMT
		Reason Code Test				DAVID MARRIOTT	
450.00	Maximum Dose	25.0 kGy	45.0 kGy	39.1 KGY	Pass	DMARRIOTT	07/03/2021 16:56:22 GMT
		Reason Code Test				DAVID MARRIOTT	

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: 08/10/2021 09:01:57 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: Clear Klens IPA

Sample Description: Sample Code: Fmp21169 52071

Lucideon Sample Number: UK212989-20476

Lucideon Report Number: UK212989-20476/ETEP **Issue Number:** 1

Date Logged: 12-Jul-2021 **Order Number:** PO400298

Date Reported: 21-Jul-2021 **Date(s) of Test(s):** 18-Jul-2021 to 18-Jul-2021

Endotoxin Test (EP)

2.6.14 Bacterial Endotoxins - Method C - Turbidimetric Kinetic Method

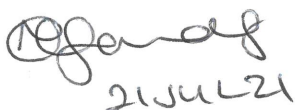
Test Results:

The test results meet the EP/USP criteria: Yes

Result: Pass (<0.2000EU/ml)

Tests carried out in accordance with cGMP

End of Test Report



21 JUL 21

Mrs Andrea Saunders

Business Support Administrator

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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: Clear Klens IPA

Sample Description: Sample Code: Fmp21169 52071

Lucideon Sample Number: UK212989-20475

Lucideon Report Number: UK212989-20475/MFEP **Issue Number:** 1

Date Logged: 12-Jul-2021 **Order Number:** PO400298

Date Reported: 03-Aug-2021 **Date(s) of Test(s):** 16-Jul-2021 to 30-Jul-2021

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



03 AUG 21

Mrs Andrea Saunders

Business Support Administrator

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